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PATENTING AROUND FAILURE

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Many patents cover inventions that do not work as described. Fingers often point to the U.S. Patent and Trademark Office (Patent Office), which is criticized for doing a poor job of examining patents. But the story is more complicated for at least three reasons. First, the Patent Office is at a clear disadvantage from an information standpoint. Inventors have little incentive to disclose failure because it might compromise patentability. Second, an inventor is not required to actually make everything that is claimed (or verify that everything that is claimed actually works) before filing a patent application. Third, inventors have an incentive to file patent applications early in the inventive process. Often, filing occurs during the initial stages of research and development, before much experimentation has been done and when the level of uncertainty is high. Together, these factors set the stage for an issued patent covering subject matter that does not work as described.

Of course, inventors continue to experiment during the years of patent examination. This additional experimentation inevitably reveals more information about the invention than the inventor knew at the time of filing, including if any of the claimed subject matter fails to work as described in the patent application. This raises an important issue that has been overlooked by both courts and scholars: When post-filing experimentation reveals that some of the claimed subject matter does not work, is there a duty to act? This Article argues when failure comes to light the inventor has a legal obligation to, at a minimum, amend the claims. It then explains how to encourage inventors to disclose details about the failure in the patent record. This additional disclosure would have several upsides for the inventor: it would improve patent (examination) quality, enrich the public storehouse of technical knowledge, and promote the broader goals of the patent system.

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INTRODUCTION

The U.S. Patent and Trademark Office (Patent Office) is often criticized for issuing a large number of questionable, "bad," or low-quality patents.[1] Patent quality can be defined as "the capacity of a granted patent to meet (or exceed) the statutory standards of patentability—most importantly, to [cover

1 *See generally* JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE (2008); DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT (2009); ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS (2004).

inventions which are] novel, nonobvious, and clearly and sufficiently described."[2] Famous examples of questionable patents include a motorized ice cream cone,[3] a method of exercising a cat with a laser pointer,[4] a snake leash,[5] and a "high-five" machine.[6] Aside from being technically invalid,[7] these patents impose costs on the legal system, competitors, would-be inventors, and society.[8]

The quality of an issued patent depends on the quality of the underlying examination.[9] The assurance of a high-quality patent examination is largely about information[10]: an examiner must have all of the relevant technical information in hand in order to accurately gauge patentability. When the issue is whether the invention works as described, the question becomes one of *enablement*, the statutory requirement that an invention be sufficiently disclosed to allow a person having ordinary skill in the art (PHOSITA)[11] to make and use it without undue experimentation.[12] From an information standpoint, the Patent Office is at a clear disadvantage because the inventor

2 R. Polk Wagner, *Understanding Patent-Quality Mechanisms*, 157 U. PA. L. REV. 2135, 2138 (2009); *cf.* Christi J. Guerrini, *Defining Patent Quality*, 82 FORDHAM L. REV. 3091, 3092-93 (2014) (defining "low-quality" or "bad" patents as those "which carve out of the public domain and deter others from practicing inventions that are in some way undeserving of patent protection"). The patentability requirements appear in Title 35 of the United States Code. Briefly, the claimed invention must be useful, novel, nonobvious, and directed to patentable subject matter. 35 U.S.C. §§ 101–103 (2012). In addition, the application must adequately describe, enable, and set forth the best mode contemplated for carrying out the invention and conclude with claims that delineate the invention with particularity. *Id.* § 112(a)–(b).

3 Motorized Ice Cream Cone, U.S. Patent No. 5,971,829 (filed Mar. 6, 1998).

4 Method of Exercising a Cat, U.S. Patent No. 5,443,036 (filed Nov. 2, 1993).

5 Collar Apparatus Enabling Secure Handling of a Snake by Tether, U.S. Patent No. 6,490,999 (filed Aug. 29, 2001).

6 Apparatus for Simulating a "High-Five," U.S. Patent No. 5,356,330 (filed Dec. 7, 1993).

7 *Cf.* FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 5 (2003) [hereinafter FTC REPORT] ("A poor quality or questionable patent is one that is likely invalid or contains claims that are overly broad.").

8 Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1515 (2001); Christopher R. Leslie, *The Anticompetitive Effects of Unenforced Invalid Patents*, 91 MINN. L. REV. 101, 113-39 (2006).

9 FTC REPORT, *supra* note 7, at 19.

10 *See* Christopher A. Cotropia, *Modernizing Patent Law's Inequitable Conduct Doctrine*, 24 BERKELEY TECH. L.J. 723, 748 (2009) ("The assurance of good patent quality is all about information . . . .").

11 The PHOSITA is a hypothetical construct of patent law akin to the reasonably prudent person in torts. Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1566 (Fed. Cir. 1987). Factors relevant to constructing the PHOSITA in a particular technical field include the sophistication of the technology, the educational level of the inventor, the educational level of active workers in the field, the types of problems encountered in the art, prior art solutions to those problems, and the rapidity with which innovations are made. Envtl. Designs, Ltd. v. Union Oil Co., 713 F.2d 693, 696 (Fed. Cir. 1983).

12 The patent document must "contain a written description of the invention . . . in such full, clear, concise, and exact terms as to *enable* any person skilled in the art to which it pertains . . . to make and use the same." 35 U.S.C. § 112(a) (2012) (emphasis added). Although the term "undue experimentation" does not appear in the statute, "it is well established that enablement requires that the specification teach those in the art to make and use the invention without undue experimentation." *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

has little incentive to disclose failure or any experimental data that might compromise patentability.[13] And since the Patent Office lacks its own testing facilities, it must rely on information presented by the inventor.[14] This information asymmetry inevitably allows nonenabled patents to slip through the cracks and further contributes to the patent quality problem.[15]

But other factors contribute to the proliferation of nonenabled patents. First, an inventor is not required to actually make everything that is claimed (or verify that everything that is claimed actually works) before filing a patent application. As discussed below, an inventor can satisfy enablement with so-called "prophetic" examples.[16] Second, for a variety of reasons, applicants have an incentive to file patent applications early in the inventive process.[17] In fields like chemistry, biotechnology, and pharmaceuticals, this means filing during the initial stages of research and development before much experimentation has been done and the level of uncertainty is high. Together, these factors set the stage for an issued patent covering subject matter that does not work as described.[18]

Of course, inventors who file early continue to experiment during the years of patent prosecution.[19] Post-filing experimentation inevitably reveals more information about the invention than the inventor knew at the time of filing, including if any of the claimed embodiments[20] fails to work as described in the patent application. This raises an important issue that has been overlooked by both courts and commentators: When post-filing experimentation during patent prosecution reveals that some of the claimed subject matter fails to work as described, is there a duty to amend the patent document or disclose the failure to the Patent Office?

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13 No one actually believes that everything that the inventor knows about the invention ends up before the examiner. *See* MARTIN J. ADELMAN ET AL., CASES AND MATERIALS ON PATENT LAW 579 (4th ed. 2015) ("Experience teaches . . . that applicant obligations of candor may be tempered by the great incentive they possess not to disclose information that might deleteriously impact their prospective patent rights.").

14 *See* discussion *infra* Part II.

15 Sean B. Seymore, *Patent Asymmetries*, 49 U.C. DAVIS L. REV. 963, 986 (2016) [hereinafter Seymore, *Patent Asymmetries*].

16 *See infra* Section I.B.

17 *See infra* text accompanying notes 36–40.

18 *See infra* Section I.A.

19 The process of obtaining a patent—where the inventor or his or her agent or attorney files an application with the Patent Office—is called patent prosecution. ALAN L. DURHAM, PATENT LAW ESSENTIALS 37 (4th ed. 2013). For fiscal year 2016, the average total pendency—the time it takes to prosecute an application from filing the first patent document to issuance—was 25.3 months. U.S. PATENT & TRADEMARK OFFICE, PERFORMANCE AND ACCOUNTABILITY REPORT FISCAL YEAR 2016, at 3 (2016).

20 An "embodiment" is a concrete, physical form of an invention described in a patent application or patent. ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 33 (7th ed. 2017).

To illustrate, consider the following hypothetical. Suppose an inventor at a drug company seeks to make a class of drugs to successfully treat arthritis. Having made one compound, *W*, which shows promising results, the inventor hypothesizes that structurally similar compounds *X*, *Y*, and *Z* (which have *not* been made) will exhibit the same or better efficacy. So the drug company files a patent application which: (1) discloses actual details about *W*; (2) discloses prophetic details about *X*, *Y*, and *Z*; and (3) claims *W*, *X*, *Y*, and *Z* and a method of treating arthritis by administering a therapeutically effective amount of the respective compound to a patient. But post-filing experimentation during the application's pendency[21] reveals that while *W* and *X* work as described, *Y* has no effect on arthritis and *Z* cannot be made. Thus, *Y* and *Z* are nonenabled.

It is unclear how the drug company should proceed. The options include:

(1) amending the written description of the invention[22] to delete details about the "inoperative" embodiments *Y* and *Z*;[23]

(2) amending the claim(s) to cancel the nonenabled subject matter; or

(3) remaining silent and allowing the patent (application) to issue as it was initially filed, thereby concealing the failure.

As the discussion below will show, the relevant law is not as clear-cut as one might hope. First, a patent applicant owes the Patent Office a duty of candor, a duty of good faith, and a duty to disclose all information material to patentability.[24] A breach of this duty is considered inequitable conduct or fraud on the Patent Office and renders the patent unenforceable.[25] Second, the U.S. Court of Appeals for the Federal Circuit[26] has reiterated that "[c]laims are not enabled when, at the effective filing date of the patent, [a PHOSITA] could not practice their *full scope* without undue

21 Patent pendency refers to the length of time between filing the patent application and patent issuance. CRAIG ALLEN NARD, THE LAW OF PATENTS 48 (4th ed. 2017).

22 The written description is the part of the patent document that completely describes the invention. 35 U.S.C. § 112(b) (2012) ("The specification shall contain a written description . . . . It shall conclude with one or more claims . . . ."). Although I will not discuss it in this Article, it is worth noting that the terms "written description" and "specification" are often used interchangeably (and mistakenly) in patent law. F. SCOTT KIEFF ET AL., PRINCIPLES OF PATENT LAW 155 n.4 (5th ed. 2011).

23 An inoperative embodiment either cannot be made or does not work as described. Thus, a claim that encompasses inoperative embodiments raises an enablement issue. Crown Operations Int'l, Ltd. v. Solutia, 289 F.3d 1367, 1380-81 (Fed. Cir. 2002).

24 *See infra* Section II.A.

25 *See infra* Section II.A.

26 The Federal Circuit has jurisdiction over appeals from the Patent Office and district court cases arising under the patent laws. The court was created by the Federal Courts Improvement Act of 1982. *See infra* note 28.

experimentation."[27] In theory, this should provide an incentive for the drug company to address the failure during patent prosecution because the claim would be vulnerable to an invalidity attack, or the defense of inequitable conduct, if it were ever asserted in patent infringement litigation. Third, notwithstanding the previous point, the Federal Circuit and its predecessor court, the U.S. Court of Customs and Patent Appeals (C.C.P.A.)[28] have held that a claim which includes *some* inoperative embodiments is not necessarily invalid for nonenablement.[29] This arguably provides an escape hatch for inventors who learn about failure during patent application pendency.

There is every reason to believe that concealment of inoperability is pervasive, thereby producing a countless number of issued patents which disclose and claim failure. This problem not only contributes to the proliferation of nonenabled (and thus low-quality) patents, but has far-reaching implications for the patent system. This Article argues that an applicant who learns about experimental failure during patent prosecution has a legal obligation to, at the very least, amend the claims.[30] It then explains how to encourage inventors to disclose details about the failure in the patent record.[31] This additional disclosure would have several upsides for the inventor,[32] improve patent (examination) quality,[33] enrich the public storehouse of technical knowledge,[34] and promote broader goals of the patent system.[35]

The remainder of the Article proceeds as follows. Part I explores the patenting of underdeveloped inventions. It explains why the patent system allows (if not encourages) inventors to do so despite the high likelihood that some of the claimed subject matter might not work as described. Part II examines experimental failure and the costs of nondisclosure on the scientific community and the patent system. In Part III, I argue that despite the murkiness of the relevant case law, a patent applicant cannot conceal known failure without breaching a duty of candor and good faith owed to the Patent Office. Next, Part IV explains how a patent applicant who learns

27 Wyeth & Cordis Corp. v. Abbott Labs, 720 F.3d 1380, 1384 (Fed. Cir. 2013) (emphasis added) (quoting MagSil Corp. v. Hitachi Global Storage Techs., Inc., 687 F.3d 1377, 1380-81 (Fed. Cir. 2012)).

28 The C.C.P.A. was a five-judge Article III appellate court on the same level as the U.S. Courts of Appeals. The Federal Courts Improvement Act of 1982 abolished the C.C.P.A. *See* Pub. L. No. 97-164, 96 Stat. 25 (codified as amended in scattered sections of 28 U.S.C.). Soon after its creation, the Federal Circuit adopted C.C.P.A. decisional law as binding precedent. *See* South Corp. v. United States, 690 F.2d 1368, 1370 (Fed. Cir. 1982) (en banc).

29 *See infra* Section III.B.

30 *See infra* Parts III and IV.

31 *See infra* Part V.

32 *See infra* Section V.B.

33 *See infra* subsection V.C.1.

34 For a discussion of the storehouse, see *infra* note 55. *See also infra* Section II.B. (explaining the role of failure in knowledge building).

35 *See infra* subsection V.C.2.

about experimental failure after filing can claim around it. Finally, Part V explains how to encourage inventors to disclose information about failure in the patent record. It explores why incentivizing such post-filing disclosures has several upsides for the patent system, including improved patent (examination) quality and furthering the broader goal of promoting technological progress.

I. PATENTING UNDERDEVELOPED INVENTIONS

While all would agree that issuing nonenabled patents is far from ideal, their proliferation is not surprising given that "the patent law[s] place[] strong pressure on filing the patent application *early* in the development of the technology, often before . . . all of the boundaries [are] fully explored."[36] Indeed, inventors must often file before actually reducing the invention to practice in order to attract investors,[37] minimize risk,[38] and to safeguard patent rights in the United States and abroad.[39]

Nevertheless, the pressure to file early essentially invites inventors to seek patents on underdeveloped inventions. This regime inevitably produces nonenabled patents which disclose and claim failure.

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36 Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1536 (Fed. Cir. 1995) (en banc) (Newman, J., concurring) (emphasis added), *rev'd on other grounds*, 520 U.S. 17 (1997); *see also* Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 267-71 (1977) [hereinafter Kitch, *Nature and Function*] (explaining the rules in patent law that force and permit early filing).

37 It is axiomatic in patent law that many inventors must rely on investors to cover the hefty costs of patent procurement and commercialization. *See* JOHN SAMSON, INVENTIONS AND THEIR COMMERCIAL DEVELOPMENT 1, 51 (1896) ("To have the use of capital is nearly always indispensable for the development of an invention, and, unless the inventor is of that fortunate class who have the means to work their own patents, he must appeal for support to one or more people with money."); Mark A. Lemley, *Reconceiving Patents in the Age of Venture Capital*, 4 J. SMALL & EMERGING BUS. L. 137, 143-44 (2000) (discussing the importance of patents as tools to attract venture capital financing); Craig Allen Nard, *Certainty, Fence Building, and the Useful Arts*, 74 IND. L.J. 759, 759 (1999) ("The prospect of certainty in the patentee's property interest has several benefits, one of which is to create a sense of security which permits the patentee to secure risk capital from investors, which in turn facilitates the commercialization of the claimed invention.").

38 *See, e.g.*, Ted Sichelman, *Commercializing Patents*, 62 STAN. L. REV. 341, 393-94 (2010) ("If building a prototype is costly—take, for example, fabricating a new type of computer chip—the risks of not securing a patent [before actual reduction to practice] may be too large to justify doing so.").

39 *See* 35 U.S.C. § 102(a) (2012) (encouraging diligence by penalizing inventors for the delayed filing of patent applications); Convention on the Grant of European Patents, art. 54(2), Oct. 5, 1973, 1065 U.N.T.S. 255, 272 (invoking an absolute novelty requirement which regards any pre-filing disclosure, including activity by the inventor, as patent defeating).

A. *Claiming the Unproven*

An inventor can obtain a patent without actually making and testing everything that is claimed.[40] It is well settled in U.S. patent law that the mental act of conception of the idea, rather than any physical act, is the important facet of the inventive process.[41] Thus, an applicant who "constructively" reduces an invention to practice by filing a patent application which describes the invention presumably has complied with the disclosure requirements of 35 U.S.C. § 112(a), including enablement.[42]

Constructive reduction to practice plays a unique role in patent law, as Judge Pauline Newman describes:

> [It] is a legal status unique to the patent art. Unlike the rules for scientific publications, which require actual performance of every experimental detail, patent law and practice are directed to teaching the invention so that it can be practiced. The inclusion of constructed examples in a patent application is an established method of providing the technical content needed to support the conceived scope of the invention.[43]

The basic tenet of constructive reduction to practice is that "[t]he invention disclosed in the patent application must be capable of actually working in the real world *if it were built*, but the inventor herself need not have yet built it, practiced it, or otherwise made it work in the real world."[44]

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40 *See In re* Angstadt, 537 F.2d 498, 502-03 (C.C.P.A. 1976) (ruling that inventors are "not required to disclose every species encompassed by their claims); *see also In re* Chilowsky, 229 F.2d 457, 461 (C.C.P.A. 1956) ("The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it."). Indeed, patent law "explicitly assumes the need for more experimentation *after* filing to actually implement the invention." Christopher A. Cotropia, *The Folly of Early Filing in Patent Law*, 61 HASTINGS L.J. 65, 93 (2009) (emphasis added) [hereinafter Cotropia, *Early Filing*].

41 Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 60-61 (1998). The inventive process requires two acts: conception and reduction to practice. 1 WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS 116 (Boston, Little, Brown & Co. 1890). Conception, often referred to as the "touchstone" of inventorship, is the "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." *Id.* at 532; *accord* Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1227-28 (Fed. Cir. 1994).

42 Reduction to practice occurs when the inventor either makes the invention and establishes that it works for its intended purpose or files a patent application which describes the invention in sufficient detail to satisfy the disclosure requirements of § 112(a), including the "how to make" prong of enablement. *See In re* Borst, 345 F.2d 851, 855 (C.C.P.A. 1965) ("[T]he disclosure must be such as will give possession of the invention to the person of ordinary skill."); *see also* Yasuko Kawai v. Metlesics, 480 F.2d 880, 886 (C.C.P.A. 1973) ("[C]onstructive reduction to practice . . . requires that there be sufficient disclosure in the specification to enable any person skilled in the art to take advantage of that utility where it would not be obvious how this is done.").

43 Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354, 1377 (Fed. Cir. 2003) (Newman, J., dissenting).

44 John F. Duffy, *Reviving the Paper Patent Doctrine*, 98 CORNELL L. REV. 1359, 1366 (2013).

Yet, courts acknowledge that the doctrine of constructive reduction to practice is legal fiction.[45] Clearly the inventor is speculating or even guessing about embodiments that have not been made.[46] Nonetheless, "the underlying assumption in patent law is that the inventor 'has' the invention mentally, and so can give a sufficiently detailed description of that inventive conception—[thus] physically creating the invention is straightforward."[47]

Since the doctrine is legal fiction, it is not surprising that constructive reduction to practice has several inherent problems. First, some inventions cannot be constructively reduced to practice because they require confirmation through experiment.[48] For example, it is often true that in "unpredictable" fields like chemistry, biotechnology, and pharmacology,[49] a patent that lacks a substantial number of working examples runs a high risk of nonenablement.[50] This is because a PHOSITA must often use trial and error—and perhaps engage in undue experimentation—to figure out how to practice the full scope of the claimed invention.[51] Second, by not requiring that the inventor have a fully developed and tested invention at the time of filing, the resulting patent will probably be too broad in scope. Put another way, the patent will likely protect

45 *See, e.g.*, Elan Pharms., Inc. v. Mayo Found., 346 F.3d 1051, 1055 (Fed. Cir. 2003) ("Even the act of publication or the fiction of constructive reduction to practice will not suffice if the disclosure [is inadequate]." (quoting *Borst*, 345 F.2d at 855)). Nonetheless, the Federal Circuit regularly reiterates that constructive reduction to practice is an established method of disclosure, even in the experimental sciences. *See* Falkner v. Inglis, 448 F.3d 1357, 1366-67 (Fed. Cir. 2006); Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 926 (Fed. Cir. 2004).

46 Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?,* 17 BERKELEY TECH. L.J. 1155, 1174 n.77 (2002) ("Of course, in the case of constructive reduction to practice . . . the inventor is in some sense speculating or guessing about the features on an invention not yet built.").

47 *Id*.

48 Courts have long recognized the differences between something like a simple mechanical device and a chemical compound. *See, e.g.*, Tyler v. Boston, 74 U.S. (7 Wall.) 327, 330 (1868) ("Now a machine which consists of a combination of devices is the subject of invention, and its effects may be calculated *a priori*, while a discovery of a new substance by means of chemical combinations of known materials is empirical and discovered by experiment."); Naylor v. Alsop Process Co., 168 F. 911, 919 (8th Cir. 1909) ("It should also be borne in mind in considering this subject that reasoning by analogy in a complex field like chemistry is very much more restricted than in a simple field like mechanics.").

49 Enablement depends on the nature of the technology. Inventions are often said to emerge from "unpredictable" or "predictable" fields. The courts refer to chemistry, biotechnology, and related experimental fields as "unpredictable" because PHOSITAs in these fields often cannot predict whether a reaction protocol that works for one embodiment will work for others. Cedarapids, Inc. v. Nordberg, Inc., No. 95-1529, 1997 WL 452801, at *2 (Fed. Cir. Aug. 11, 1997) (explaining that in the chemical arts, "a slight variation . . . can yield an unpredictable result or may not work at all"). By contrast, applied technologies like electrical and mechanical engineering are often regarded as "predictable" arts because they are rooted in well-defined, predictable factors. *In re* Vaeck, 947 F.2d 488, 496 (Fed. Cir. 1991).

50 *See, e.g.*, *In re* Prutton, 200 F.2d 706, 712 (C.C.P.A. 1952) (holding that claims to a class of chemical compounds, which were sufficiently broad to involve some speculation, lacked enablement despite the presence of specific examples within the class).

51 Sean B. Seymore, *The Teaching Function of Patents*, 85 NOTRE DAME L. REV. 621, 644-45 (2010) [hereinafter Seymore, *Teaching Function*].

speculative ideas as opposed to subject matter that is truly enabled.[52] Third, these patents can create insurmountable roadblocks (intentionally or not)[53] for others with meritorious inventions.[54] Finally, the disclosure of unproven ideas arguably adds little or nothing to the public storehouse of knowledge.[55]

B. *Prophetic Examples*

Since an applicant's compliance with § 112(a) does not turn on the amount of actual pre-filing experimentation done,[56] the courts allow inventors to satisfy enablement in other ways. These include the use of prophetic examples, which Timothy Holbrook defines as "forms of the invention that the patentee did not actually invent but which would be within the scope of her disclosure."[57] A patent supported with prophetic examples does not

52 *Cf.* Christopher A. Harkins, *Fending Off Paper Patents and Patent Trolls: A Novel "Cold Fusion" Defense Because Changing Times Demand It*, 17 ALB. L.J. SCI. & TECH. 407, 453 (2007) (explaining that the lack of a requirement for an inventor to "actually have a complete and operative invention . . . [at the time of filing increases the] potential that the [claims] will protect speculative ideas . . . . With just a little time, money, and imagination, one may [obtain a patent] . . . without inventing anything . . . .").

53 For instance, so-called "nuisance" prior art describing an unworkable invention "can . . . be generated as a result of a bona fide attempt at a constructive reduction to practice that for some unexpected reason fails to work as disclosed." David S. Wainwright, *Patenting Around Nuisance Prior Art*, 81 J. PAT. & TRADEMARK OFF. SOC'Y 221, 223-24 (1999). Innocuously disclosed information which has the same effect is often described as "technical junk." *Id.* at 222, 223 n.3.

54 A good example is when an early filer strategically drafts claims which cover undeveloped technology. *See* BESSEN & MEURER, *supra* note 1, at 67 (arguing that the practice "penalizes real innovators who operate in the shadow of early, broad claims"); Wainwright, *supra* note 53, at 222 (explaining how nuisance prior art can discourage applicants to the point of abandoning their patent applications); *see also* Michael J. Meurer & Craig Allen Nard, *Invention, Refinement and Patent Claim Scope: A New Perspective on the Doctrine of Equivalents*, 93 GEO. L.J. 1947, 1975 (2005) (exploring the practice and discussing how patent prosecutors draft claims to "mitigate problems with language and later-developed technology").

55 *See In re* Argoudelis, 434 F.2d 1390, 1394 (C.C.P.A. 1970) (Baldwin, J., concurring) (explaining that the full and complete disclosure of how to make and use the claimed invention "adds a measure of worthwhile knowledge to the public storehouse"); *cf.* Mark A. Lemley, *Ready for Patenting*, 96 B.U. L. REV. 1171, 1186 (2016) (explaining that patents which lack technical detail and experimental results because nothing has been made are unhelpful to scientists).

56 *See In re* Borkowski, 422 F.2d 904, 908 (C.C.P.A. 1970) (explaining that there is no statutory basis for a "working example" requirement); *In re* Long, 368 F.2d 892, 894-95 (C.C.P.A. 1966) (emphasizing that there is no "specific embodiment" requirement).

57 Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 158 (2006) [hereinafter Holbrook, *Possession*]; *see also* U.S. PATENT & TRADEMARK OFF., MANUAL OF PATENT EXAMINING PROCEDURE § 608.01(p) (9th ed. 8th rev., Jan. 2018) [hereinafter MPEP] (permitting the use of prophetic examples). A key benefit of prophetic examples is their use in provisional patent applications. A provisional application allows an applicant to obtain an early filing date for the invention before the applicant is ready to draft a claim or a full application. *See* 35 U.S.C. § 111(b) (2012) (allowing a provisional application, in which no claim is required). But the provisional application must satisfy the disclosure requirements of § 112(a), including enablement. *See* New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co., 298 F.3d 1290, 1294 (Fed. Cir. 2002) ("Such a provisional application need only include a specification conforming to the requirements of 35 U.S.C. § 112 and at least one drawing filed under § 113; no claims are required.").

necessarily raise any red flags with respect to (non)enablement.[58] In fact, the Federal Circuit is quite receptive to them:

> [A] patent does not need to guarantee that the invention works for a claim to be enabled. It is well settled that an invention may be patented before it is actually reduced to practice. . . . Similarly, a patentee is not required to provide actual working examples; we have rejected enablement challenges based on the theory that there can be no guarantee that prophetic examples actually work . . . .[59]

Yet prophetic examples have several serious drawbacks. First, they are often less helpful than working examples, particularly in the unpredictable fields discussed above.[60] For example, in chemistry a PHOSITA often cannot take a result from one reaction and predict how similar compounds will react with any reasonable expectation of success.[61] This is true, as illustrated in the hypothetical set forth in the Introduction,[62] because minor changes in chemical structure can result in large changes in reactivity.[63] Second, the mere ability to craft prophetic examples does not mean that the inventor necessarily *possesses* the (full scope of the) invention.[64] Third, and relatedly, it is almost inevitable that some of the prophetically claimed subject matter will not work as described—particularly in

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58 *See* Atlas Powder Co. v. E.I. Du Pont de Nemours & Co., 750 F.2d 1569, 1577 (Fed. Cir. 1984). Patentees must set forth prophetic examples in the present tense to signal that they were not carried out. Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1376 n.1 (Fed. Cir. 2003) (citing *Atlas Powder*, 750 F.2d at 1578).

59 Alcon Res. Ltd. v. Barr Labs., Inc., 745 F.3d 1180, 1189 (Fed. Cir. 2014) (citing Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 61 (1998)); *cf. In re* Anderson, 471 F.2d 1237, 1240-41 (C.C.P.A. 1973) (explaining that since § 112 does not require a specific example for everything encompassed by a claim, the Patent Office cannot limit the scope of a claim to the specific examples disclosed).

60 *See supra* note 49 and accompanying text.

61 *See* Sean B. Seymore, *Heightened Enablement in the Unpredictable Arts*, 56 UCLA L. REV. 127, 144-46 (2008) [hereinafter Seymore, *Heightened Enablement*] (emphasizing that, in chemistry, the "array of chemical compounds which are structurally similar may differ radically in their properties"); *cf. In re* Wright, 999 F.2d 1557, 1564 (Fed. Cir. 1993) (testing enablement by determining if a skilled scientist working with RNA viruses would have reasonably believed that the inventor's success with the described embodiment(s) "could be extrapolated with a reasonable expectation of success" to other embodiments encompassed by the claims).

62 *See supra* notes 22–24 and accompanying text.

63 The courts recognized long ago that chemical compounds similar in structure can differ radically in their properties, even when they belong to the same chemical class. If an applicant seeks to claim the class, "it must appear in the [written description] . . . that the chemicals or chemical combinations included therein [are] generally capable of accomplishing the desired result." *In re* Walker, 70 F.2d 1008, 1011 (C.C.P.A. 1934) (internal quotation marks omitted).

64 *See* Holbrook, *Possession*, *supra* note 57, at 146 ("One could describe an idea but not necessarily truly be in possession of it."). The question of possession is closely tied to enablement. Indeed, the Federal Circuit has observed that "a recitation of how to make and use the invention across the full breadth of the claim is ordinarily sufficient to demonstrate that the inventor possesses the full scope of the invention." LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1345 (Fed. Cir. 2005).

unpredictable fields.[65] As noted above, this can frustrate the efforts of other researchers who can actually enable the prophetically-claimed invention.[66]

C. *The Role of Enablement*

In theory, a patent that *claims* failure is invalid.[67] To be sure, "an applicant cannot possibly enable a PHOSITA to practice an invention that does not work."[68] To understand why, it necessary to briefly explain enablement and the role it plays in patent law.

Enablement is the patentability requirement which "lies at the heart of the patent bargain."[69] By compelling an applicant to prepare a written description of the invention[70] sufficient to teach a PHOSITA how to make and use it without undue experimentation,[71] enablement ensures that the applicant's disclosure sufficiently enriches the public storehouse of technical knowledge[72] and that the public will get complete possession of the invention once the patent expires.[73] It polices claim scope[74] and safeguards patent law's disclosure function.[75]

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65 Seymore, *Teaching Function*, *supra* note 51, at 632.

66 *See supra* notes 53–54 and accompanying text.

67 *See supra* note 27 and accompanying text. But there is a place for experimental failure in patent law. I have argued elsewhere that including information about failure in the patent document supports patent law's disclosure function. *See* Sean B. Seymore, *The Null Patent*, 53 WM. & MARY L. REV. 2041, 2048 (2012) (proposing the creation of nonexclusionary patent documents known as "null patents" which would disseminate technical information harvested from failed experiments). Gideon Parchomovsky and Michael Mattioli have proposed an alternative, opt-in type of patent that requires the disclosure of all research results (including experimental failure) as a precondition for issuance. *See* Gideon Parchomovsky & Michael Mattioli, *Partial Patents*, 111 COLUM. L. REV. 207, 229-33 (2011) ("Information about failed research attempts can be just as valuable to fellow researchers as the details of successes.").

68 Sean B. Seymore, *Patently Impossible*, 64 VAND. L. REV. 1491, 1501 (2011).

69 1 DONALD S. CHISUM, CHISUM ON PATENTS § 7.01 (2012); *cf. LizardTech*, 424 F.3d at 1344-45 (describing enablement as the essential aspect of the patent bargain).

70 *See supra* note 22.

71 *See supra* note 12 and accompanying text.

72 *See supra* note 55; *see also* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 481 (1974) (explaining that when the information disclosed in a patent becomes publicly available it adds to the "general store of knowledge" and assumedly will stimulate ideas and promote technological development).

73 Evans v. Eaton, 20 U.S. (7 Wheat.) 356, 418 (1822).

74 Claim scope is the "technological territory" that the inventor claims is his or hers to control. Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 844 (1990). The enablement provided in the patent document serves as a constraint on claim scope. O'Reilly v. Morse, 56 U.S. (15 How.) 62, 121 (1854); *see also* Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999) (noting that enablement's purpose is to "ensure[] that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims"). The scope of enablement is the sum of what is taught in the written description plus a PHOSITA's knowledge. *Id.*

75 FTC REPORT, *supra* note 7, ch. 4, at 3-4.

Enablement is a standard.[76] Determining whether a disclosure was enabling as of its filing date[77] is a legal conclusion that rests on underlying factual inquiries.[78] The Federal Circuit set forth several factors relevant to the enablement analysis in *In re Wands*.[79] They are: (1) the amount of direction or guidance presented in the disclosure, (2) the existence of working examples, (3) the nature of the invention, (4) the predictability or unpredictability of the art, (5) the PHOSITA's level of skill, (6) the state of the prior art (preexisting knowledge and technology already available to the public[80]), (7) the breadth of the claims, and (8) the quantity of experimentation necessary to practice the claimed invention.[81] While not mandatory,[82] the *Wands* factors are ubiquitous in evaluating enablement[83]—probably because they touch on issues that are important in virtually all enablement determinations.[84] These include issues related to the technical scope and substance of the disclosure (factors one and two),[85] the nature of the technology (factors three and four),[86] the PHOSITA's knowledge and skill (factor five),[87] and the scope of the claim sought (factor seven).[88]

Given that a principal goal of enablement is to ensure that a PHOSITA can practice the invention as broadly as it is claimed,[89] a robust enablement analysis *should*—at least in theory—ferret out inoperative embodiments. However, the *Wands* factors show that enablement is an information-

76 *See* Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1576-77 (Fed. Cir. 1984) (concluding that enablement does not require specific exclusion of inoperative combinations for claims to remain valid); Seymore, *Heightened Enablement*, *supra* note 61, at 130 (noting that current framework flexibility may allow broad claims to be enabled by even trivial amounts of disclosure).

77 MagSil Corp. v. Hitachi Glob. Storage Techs., Inc., 687 F.3d 1377, 1380 (Fed. Cir. 2012) ("The enablement determination proceeds as of the effective filing date of the patent.").

78 Sitrick v. Dreamworks, LLC, 516 F.3d 993, 999-1000 (Fed. Cir. 2008).

79 858 F.2d 731, 737 (Fed. Cir. 1988).

80 *See* Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1453 (Fed. Cir. 1984) (defining prior art) (citing Graham v. John Deere Co., 383 U.S. 1, 6 (1966)). For a deeper discussion of prior art and its use in gauging patentability, see *infra* note 271 and accompanying text.

81 *Wands*, 858 F.2d at 737 (factors reordered from original text).

82 Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1213 (Fed. Cir. 1991) (noting that the *Wands* factors are illustrative and not mandatory).

83 *See* 3 CHISUM, *supra* note 69, § 7.03 (collecting cases).

84 The *Wands* factors are interrelated. For example, if the PHOSITA is knowledgeable (factor five), an applicant need not disclose what the PHOSITA already knows or can easily figure out (factors one and two). *See* Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1534 (Fed. Cir. 1987) (noting that moly-manganese brazing, a well-known technique at the time of filing, did not need to be disclosed.).

85 The two factors are clustered together because working examples are a form of guidance. Seymore, *Teaching Function*, *supra* note 51, at 641-46 (describing the importance of working examples in teaching innovators in the field and therefore limiting claim scope).

86 *See supra* note 49 (discussing predictable and unpredictable technologies).

87 This factor has become increasingly important over the past decade as the Federal Circuit has compelled patentees to enable the full scope of the claimed invention. *See infra* notes 204 and 205.

88 Enablement places an outer limit on claim scope. *See supra* note 74.

89 *See supra* note 12 and accompanying text.

demanding inquiry that intensifies as the subject matter becomes more complex.[90] Still, since the Patent Office lacks its own testing facilities and has no way to verify if the claimed subject matter actually works, the robustness of the enablement analysis is limited by information provided by the applicant during patent prosecution.[91] As such, to the extent that the Patent Office suffers from an information deficit, the agency will inevitably issue patents that disclose and claim failure. If post-filing experimentation has been done, this problem can be mitigated because applicants now know more about which embodiments work and which ones are inoperative. As discussed below, the challenge is to get this knowledge into the examiner's hands.[92]

II. UNDERSTANDING EXPERIMENTAL FAILURE

A. *The Ubiquity of Failure in Science*

Failure abounds in scientific research.[93] An experiment fails when it does not produce the expected outcome.[94] This can happen because of poor experimental design, sloppy research technique, a flawed hypothesis, or for reasons unknown:

> No matter how well understood the theories leading up to the experiments are or how well-designed those experiments are or how carefully the experiments are done, the end result often is nothing like what was expected. The results can be thought of as failures or as a learning that the plan was based on an unknown flaw. Experimental science delves into the unknown, so the work beforehand is a best guess at what might be. Sometimes these

90 Peter Lee, *Patent Law and the Two Cultures*, 120 YALE L.J. 2, 67 (2010) (noting that long lists of factors can raise information costs instead of reducing them). To be sure, it is easier to gauge enablement in simple inventions like paper clips and broom rakes than in more complex inventions like chemical compounds. Sean B. Seymore, *The Presumption of Patentability*, 97 MINN. L. REV. 990, 1019 (2013).

91 *See infra* note 142 and accompanying text.

92 *See infra* Section II.A.

93 STUART FIRESTEIN, FAILURE: WHY SCIENCE IS SO SUCCESSFUL 41 (2015) (explaining that "failure is the default" in scientific research because "[t]here are many more ways to fail than to succeed"). Here I should distinguish *failure* from *mistake*—the latter describing a situation where the experiment produces the correct outcome but the result is misidentified due to a misunderstanding of the relevant science. *See* Cubist Pharms., Inc. v. Hospira, Inc., 805 F.3d 1112, 1115-19 (Fed. Cir. 2015) (upholding the Patent Office's decision to issue a certificate of correction for a patent which misidentified a chemical structure because it was universally believed at the time of filing that the misidentified structure was proper and that the post-issuance correction did not broaden the scope of the claims).

94 *See* Jonathan Knight, *Null and Void*, 422 NATURE 554, 554-55 (2003) (investigating the fate of negative results). In this Article, the terms *negative results* and *failed experiment* are used interchangeably to include experiments that do not work as planned.

> best guesses end up being totally wrong and the series of experiments yield nothing other than the fact that there is something unexplained.[95]

Regardless of the cause, in science it is often the case that experiments do not work as planned.[96] In fact, negative results comprise the bulk of knowledge produced in scientific research.[97]

B. *The File Drawer Problem*

The problem with data generated from failed experiments is that most of it is never disclosed.[98] Negative results comprise 10–30% of the published scientific literature, depending on the technical field.[99] This is true even though failure plays a key role in knowledge building[100] and forces researchers to think critically and (re)evaluate current thinking.[101] The practice of nondisclosure is often called the "file drawer problem"[102] because it is

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95 JOHN FETZER, CAREER MANAGEMENT FOR CHEMISTS: A GUIDE TO SUCCESS IN A CHEMISTRY CAREER 14-15 (2004); *see also* RICHARD H. MCCUEN, THE ELEMENTS OF ACADEMIC RESEARCH 275-77 (1996) (explaining why experiments fail). Sometimes the flaw comes to light when an independent researcher unsuccessfully attempts to replicate the original researcher's results using the same experimental methods and techniques. Jacob S. Sherkow, *Patent Law's Reproducibility Paradox*, 66 DUKE L.J. 845, 854 (2017). Irreproducibility provides "good reason to doubt the original result, even if the prior work was subjected to the peer-review process." *Id.*

96 MCCUEN, *supra* note 95, at 51-53; *see also* FETZER, *supra* note 95, at 15 ("[G]ood science inherently is full of failed experiments."). But as one commentator explains, (the risk of) failure makes success look much better:

> There is yet another, and perhaps not so obvious, way in which failure is key to the scientific enterprise . . . . [H]ow reliable is success if there is no sufficient possibility of failure? Success becomes more successful, and often more interesting, the harder it is to obtain, the more likely the process that led to it could have led instead to failure.

FIRESTEIN, *supra* note 93, at 63-64.

97 FIRESTEIN, *supra* note 93, at 146; Chris Patil & Vivian Siegel, *Shining a Light on Dark Data*, 2 DISEASE MODELS & MECHANISMS 521, 521 (2009) (noting that scientists spend most of their time producing unpublished negative results); *see also supra* note 95.

98 *Cf.* David Alcantara, Joe Blois & Carlos Juan Ceacero, Editorial, 1 ALL RESULTS J. BIOLOGY 1, 1 (2010), http://www.arjournals.com/index.php/Biol/article/view/40/34 [https://perma.cc/6TX3-2RQK] (describing the "huge untapped resource of experimental data locked up in laboratory notebooks that could be of great service to the scientific community").

99 *Trouble at the Lab*, THE ECONOMIST (Oct. 19, 2013), https://www.economist.com/news/briefing/21588057-scientists-think-science-self-correcting-alarming-degree-it-not-trouble [https://perma.cc/7L86-NDTP].

100 *See* DOROTHY LEONARD-BARTON, WELLSPRINGS OF KNOWLEDGE: BUILDING AND SUSTAINING THE SOURCES OF INNOVATION 119-20 (1998) (presenting stories of "failing forward" from scientific research, which is defined as "creating forward momentum with the learning derived from failures").

101 Natalie Matosin et al., *Negativity Towards Negative Results: A Discussion of the Disconnect Between Scientific Worth and Scientific Culture*, 7 DISEASE MODELS & MECHANISMS 171, 171 (2014).

102 Robert Rosenthal, *The "File Drawer Problem" and Tolerance for Null Results*, 86 PSYCHOL. BULL. 638, 638 (1979) (coining the term).

imagined that scientists bury negative results deep in their file drawers—never to see the light of day.[103]

The file drawer problem has several causes. First, a researcher might be less inclined to invest time and energy in writing up failed experiments out of a sense that the scientific community tends to be more interested in positive findings than negative ones.[104] Second, some researchers simply do not want competitors to know the seemingly fruitless paths that they have been exploring.[105]

Third, a researcher often has little incentive to disclose negative results in the mainstream, peer-reviewed technical literature.[106] A researcher writes up results in a manuscript hoping for ultimate publication in a prestigious journal.[107] And it is no secret that in most fields, acceptance by a prestigious journal is more likely if the results are positive—meaning that they support the experimental hypothesis.[108] So disclosing negative results runs the risk of tainting the research project as inferior—despite the novelty and integrity of the work—or not conforming to the reviewers' expectations.[109] Either form of publication bias could mean the "kiss of death" for the manuscript[110] or its delayed publication

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103 Donald Kennedy, *The Old File Drawer Problem*, 305 SCIENCE 451, 451 (2004); *see also* 1 ENCYCLOPEDIA OF RESEARCH DESIGN 491 (Neil J. Salkind ed., 2010) ("The file drawer problem . . . arose from the image that . . . nonsignificant results are placed in researchers' file drawers, never to be seen by others."); Daniele Fanelli, *Do Pressures to Publish Increase Scientists' Bias? An Empirical Support from US States Data*, PLoS ONE, 1 (Apr. 21, 2010), http://www.plosone.org/article/info:doi/10.1371/journal.pone.0010271 [https://perma.cc/S9ZD-PN6R] (attributing the term to the notion that unpublished "negative papers are imagined to lie in scientists' drawers").

104 Knight, *supra* note 94, at 554; Matosin et al., *supra* note 101, at 171 ("Rather than approaching a research question in a systematic manner, it seems that scientists are encouraged to pursue non-linear lines of investigation in search of significance . . . many are known to tuck away negative findings (the 'file drawer' effect) and focus on their positive outcomes.").

105 Knight, *supra* note 94, at 554.

106 Peter Hernon & Candy Schwartz, *Peer Review Revisited*, 20 LIBR. & INFO. SCI. RES. 1, 1 (2006). The mechanics of peer review typically works as follows. First, the researcher submits the work to a journal. Second, the editor of the journal sends it to one or more reviewers knowledgeable about the problem to judge its merit (uniqueness, methodology, adequacy of research design, and potential contribution to the field). Third, the editor makes a final publication decision.

107 Patil & Siegel, *supra* note 97, at 522.

108 Fanelli, *supra* note 103, at 1; Matosin et al., *supra* note 101, at 171-73.

109 David Alcantara & Rafael Prado Gotor, Editorial, 1 ALL RESULTS J. CHEMISTRY 1, 1-2 (2010), http://www.arjournals.com/ojs/index.php/Chem/article/view/38/27 [https://perma.cc/T4UA-VT5D] (exploring "submission bias," which leads researchers to publish only positive results because they "want their competitors to think they succeed at every project designed"); Stan Szpakowicz, *Failure Is an Orphan (Let's Adopt)*, 36 COMPUTATIONAL LINGUISTICS 157, 157-58 (2010).

110 Szpakowicz, *supra* note 109, at 157-58.

and relegation to a less-prestigious journal.[111] Publishing negative results in the peer-reviewed literature can have negative career consequences.[112]

Nondisclosure is an even bigger problem for industrial inventors, who publish less frequently than their academic counterparts.[113] The highest priority for them is to generate results that show commercial promise and will ultimately find their way into a marketable product.[114] Writing up results—good or bad—is often considered too costly.[115] So one might expect these inventors to draft technical documents, including patents, with as little information as possible.[116]

C. *The Costs of Nondisclosure*

The file drawer problem has potentially far-reaching implications for science and patent law. *All* research endeavors—including failed experiments—produce worthwhile technical information.[117] Indeed,

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111 Alcantara & Gotor, *supra* note 109, at 1 ("[P]ositive results have a better chance of being published, are published earlier, and are published in journals with higher impact factors."); Richard Smith, *Peer Review: A Flawed Process at the Heart of Science and Journals*, 99 J. ROYAL SOC'Y MED. 178, 180 (2006) (describing the bias against work that discloses negative results).

112 One commentator explains how:

> Since papers reporting positive results attract more interest and are cited more often, journal editors and peer reviewers might tend to [favor] them, which will further increase the desirability of [publishing] a positive outcome to researchers, particularly if their careers are evaluated by counting the number of papers listed in their CVs and the impact factor of the journals they are published in.

Fanelli, *supra* note 103, at 1.

113 *See* Benoît Godin, *Research and the Practice of Publication in Industries*, 25 RES. POL'Y 587, 588-90 (1996) (comparing publishing and patenting habits in industry and academia and demonstrating that industry papers make up a small percentage of papers published).

114 Partha Dasgupta & Paul A. David, *Information Disclosure and the Economics of Science and Technology*, *in* ARROW AND THE ASCENT OF MODERN ECONOMIC THEORY 519, 529-30 (George R. Feiwel ed., 1987).

115 Diana Hicks, *Published Papers, Tacit Competencies and Corporate Management of the Public/Private Character of Knowledge*, 4 INDUS. & CORP. CHANGE 401, 412 (1995) ("After all, writing papers makes no money and consumes time.").

116 To be sure, inventors have plenty of incentives to disclose as little as possible. *See* Wagner, *supra* note 2, at 2150-51 (discussing factors that lead applicants to "defer clarity" on their disclosures); *see also* H. JACKSON KNIGHT, PATENT STRATEGY FOR RESEARCHERS AND RESEARCH MANAGERS 88-89 (2d ed. 2001) (explaining how much information an inventor should disclose).

117 *See* LEONARD-BARTON, *supra* note 100 and accompanying text; *see also* FIRESTEIN, *supra* note 93, at 42 ("[K]nowing that something doesn't work can be as valuable as knowing that it does."). As the great science philosopher Karl Popper once wrote:

> Refutations have often been regarded as establishing the failure of a scientist, or at least of his theory. It should be stressed that this is an inductivist error. Every refutation should be regarded as a great success . . . . Even if a new theory . . . should meet an early death, it should not be forgotten; rather its beauty should be remembered, and history should record our gratitude to it.

KARL POPPER, CONJECTURES AND REFUTATIONS: THE GROWTH OF SCIENTIFIC KNOWLEDGE 243 (2002).

innovators can learn a lot from failure.[118] Since scientific publications and patent documents are both major sources of technical information,[119] nondisclosure frustrates the shared goal of science and patent law of promoting technological progress by disseminating knowledge.[120]

There is no doubt that nondisclosure is costly—both in time and money—when other researchers waste resources on experiments that have failed previously.[121] One commentator provides an excellent example of how this might happen:

> [Y]ou might think that Compound X will prevent Cancer Z from metastasizing. But if your experiments show that Compound X does *not* prevent Cancer Z from metastasizing, you have a negative result . . . . If other researchers are also really interested in Compound X, they would probably want to know that your experiments showed Compound X was ineffective. That way they could make an informed decision about how (or whether) to proceed with their own Compound X experiments. But they probably won't find out about your Compound X experiments, because most negative results never get published.[122]

This scenario yields a publication that tells an incomplete story of a research project in which the scientifically obvious—but undisclosed—path failed and a not-so-obvious path worked. Other scientists may look at the work and ask why the original researchers did not follow the obvious path and then proceed to redo the failures.[123] Thus, concealing failure sets up other researchers to do a wasted redundancy.[124]

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118 *Cf.* STEFAN H. THOMKE, EXPERIMENTATION MATTERS: UNLOCKING THE POTENTIAL OF NEW TECHNOLOGIES FOR INNOVATION 23 (2003) ("Innovators learn from failure . . . . [K]nowledge of either failure or success itself can be stockpiled, providing a resource that, if not applicable to one set of experiments, can be used for subsequent inquiries."); William J. Broad, *Taking Lessons From What Went Wrong*, N.Y. TIMES, July 20, 2010, at D1 ("Disaster, in short, can become a spur to innovation.").

119 Seymore, *Teaching Function*, *supra* note 51, at 624 (explaining that like technical journals, patents show the state of technology, reveal what has already been done, and provide technical information that others can avoid repeating). THOMAS T. GORDON & ARTHUR S. COOKFAIR, PATENT FUNDAMENTALS FOR SCIENTISTS AND ENGINEERS 51 (2d ed. 2000).

120 *See* KELLY MORE, DISRUPTING SCIENCE 2 n.5 (2008) ("Science is considered to be simultaneously a body of knowledge . . . and the means by which knowledge is acquired and disseminated."); *see also* Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 151 (1989) (stating that "the ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure").

121 There are several well-publicized examples. *See, e.g.*, Sharon Begley, *New Journals Bet "Negative Results" Save Time, Money*, WALL STREET J., Sept. 15, 2006, at B1 (describing how publication bias suppressing negative results regarding an alleged link between oral contraceptives and cervical cancer led to erroneous conclusions and wasted time and money). Sometimes withholding negative results is deliberately done to make competitors squander their resources.

122 Matt Shipman, *The Challenge of Negative Results*, SCIENTIFIC COMMUNICATION BREAKDOWN (May 28, 2013), http://www.scilogs.com/communication_breakdown/negative-results/ [https://perma.cc/J6CZ-D4YK].

123 FETZER, *supra* note 95, at 17-18.

124 *Id.*

A related concern is that withholding negative results can overrepresent the rate of success—or mask problems—in a particular technical field.[125] The incomplete information can improperly skew debates,[126] lead to an imprudent allocation of resources,[127] or even jeopardize public welfare.[128]

Perhaps the biggest drawback is that nondisclosure causes a drag on scientific progress.[129] Admitting and reporting negative results keeps scientists honest; and staying honest "is the whole point of science."[130] But aside from that, negative results "serve to drive the scientific method forward by showing the path *not* to follow."[131] Other scientists could possibly fix the error or use the failed experiment as a building block for other scientific endeavors.[132] But

125 Emma Granqvist, *Looking at Research from a New Angle*, ELSEVIER CONNECT (May 11, 2015), https://www.elsevier.com/editors-update/story/publishing-ethics/looking-at-research-from-a-new-angle [https://perma.cc/7LM6-MB2K] ("Ignoring the vast information source that is negative results is troublesome . . . . it skews the scientific literature by only including chosen pieces of information.").

126 *See, e.g.*, Knight, *supra* note 94, at 554 (noting how the nonpublication of negative results pertaining to genetically modified crops has skewed the debate; suggesting that there are no adverse health effects or environmental consequences).

127 For example, a funding agency might decide to approve a research proposal that it otherwise would deny if the agency knew the full story of the research project. BERNARD LO, ETHICAL ISSUES IN CLINICAL RESEARCH: A PRACTICAL GUIDE 113 (2010) (explaining how withholding negative results wastes scarce resources because it can direct funding away from more meritorious research projects).

128 To illustrate, a pharmaceutical company conducting clinical trials for a new drug deliberately suppressed negative results to make the drug appear safer and more effective than it really was. *See* David Egilman & Emily Ardolino, *The Pharmaceutical Industry, Disease Industry: A Prescription for Illness and Death*, *in* THE BOTTOM LINE OR PUBLIC HEALTH: TACTICS CORPORATIONS USE TO INFLUENCE HEALTH AND HEALTH POLICY, AND WHAT WE CAN DO TO COUNTER THEM 193, 193-201 (William H. Wiist ed., 2010) (explaining how Merck's suppression of Vioxx's negative cardiovascular side effects led to adverse events in patients including bleeding, heart attacks, and death); FIRESTEIN, *supra* note 93, at 148-49 (discussing Vioxx and Merck's decision to strategically withhold negative results to increase the likelihood of FDA approval).

129 Thomas Goetz, *Freeing the Dark Data of Failed Science Experiments*, WIRED MAGAZINE (Sept. 26, 2007), http://www.wired.com/science/discoveries/magazine/15-10/st_essay [https://perma.cc/7652-EAPD]; *see also* Erick H. Turner et al., *Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy*, 358 NEW ENG. J. MED. 252, 259 (2008) (arguing that the nondisclosure of negative results in drug studies "hinders the advancement of medical knowledge").

130 FIRESTEIN, *supra* note 93, at 149 (citing RICHARD P. FEYNMAN, "SURELY YOU'RE JOKING, MR. FEYNMAN!": ADVENTURES OF A CURIOUS CHARACTER 341) (1985) ("The idea is to try to give *all* the information to help others to judge the value of your contribution; not just the information that leads to judgment in one particular direction or another.").

131 Alcantara et al., *supra* note 98, at 1 (emphasis added).

132 As one commentator has explained, "The best failures produce[] an abundance of data, and, at the very least, a failed experiment eliminate[s] whatever approach to a problem was under consideration and thereby ma[kes] way for some alternative." ALAN AXELROD, EDISON ON INNOVATION 40-41 (2008); *cf.* FIRESTEIN, *supra* note 93, at 33 ("Failures . . . don't just lead to a discovery by providing a correction . . . they lead to a fundamental change in the way we think about future experiments as well . . ."). *See also* Fanelli, *supra* note 103, at 1 ("[A]ll [experimental] results are equally relevant to science"); ANDREW HARGADON, HOW BREAKTHROUGHS HAPPEN 55 (2003) (describing the role of failed experiments in innovation).

nondisclosure condemns this valuable technical information to the sea of squandered knowledge.[133]

Nondisclosure also creates problems for the patent system. Concealment of failure creates an information deficit in the public storehouse of technical knowledge.[134] This is important because determining whether an invention satisfies the substantive standards of patentability depends on what the inventor discloses and its relation to extant knowledge and potential contribution to the storehouse.[135] When technical information is concealed, it can cause all sorts of problems—including misgauging patentability[136] and hindering innovation.[137] It is also true that much technical information not disclosed through the patent system will never enter the public storehouse of knowledge and will likely be lost.[138]

III. CAN AN INVENTOR CONCEAL FAILURE?

Although concealment of failure continues to be the norm in the peer-reviewed technical literature,[139] the aforementioned costs have sparked discussions and bit of movement in the academy toward full disclosure.[140] The

133 *See* P. Bryan Heidorn, *Shedding Light on the Dark Data in the Long Tail of Science*, 57 LIB. TRENDS 280, 284-87 (2008) (describing the benefits of bringing "dark data" to light); Alcantara et al., *supra* note 98, at 1 ("There is a huge untapped resource of experimental data locked up in laboratory notebooks that could be of great service to the scientific community.").

134 *See In re* Argoudelis, 434 F.2d 1390, 1394 (C.C.P.A. 1970) (discussing the "storehouse" of knowledge).

135 A patent can only be awarded for technical advances which add to or enrich the storehouse. *See* Graham v. John Deere Co., 383 U.S. 684, 688 (1966) ("Innovation, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must 'promote the Progress of useful Arts.'"); Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1195-96 (Fed. Cir. 1999) (noting that the purpose of the enablement requirement is to ensure enrichment of public knowledge).

136 *See* Seymore, *Patent Asymmetries*, *supra* note 15, at 991 ("Clearly an examiner must have all of the relevant technical information in hand in order to accurately gauge patentability.").

137 *See supra* notes 118 and 132 and accompanying text.

138 Most information disclosed in a patent document does not appear in another medium. *See* Esteban Burrone & Guriqbal Singh Jaiya, Intellectual Property (IP) Rights and Innovation in Small and Medium-Sized Enterprises 3 (unpublished manuscript) http://www.wipo.int/export/sites/www/sme/en/documents/pdf/iprs_innovation.pdf [https:/perma.cc/UWQ6-MXUX] ("It has been estimated that patent documents contain 70% of the world's accumulated technical knowledge and that most of the information contained in patent documents is either never published elsewhere or is first disclosed through the publication of the patent application."); Seymore, *Teaching Function*, *supra* note 51, at 666 (discussing situations in which "the patent system is the sole medium of disclosure").

139 FETZER, *supra* note 95, at 17-18.

140 For instance, a growing number of prestigious medical journals like the *New England Journal of Medicine* and the *Journal of the American Medical Association* refuse to publish research involving clinical trials unless all of the data is disclosed beforehand in a public registry. *See* Catherine De Angelis et al., *Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors*, 351 NEW ENG. J. MED. 1250, 1250 (2004) (presenting the new publication policy of the International Committee of Medical Journal Editors member journals). Also, some publishers have created journals whose sole purpose is to disclose negative results, including *The All Results Journals*, http://arjournals.com/; *Journal of Negative Results*, http://www.jnr-eeb.org/index.php/jnr; *Journal of Pharmaceutical Negative Results*,

story is a bit more complicated for patent law. Below I explain why an applicant must act if inoperable subject matter is *claimed* in a patent.

A. *The Patent Applicant's Duty of Disclosure*

Patent applicants know more about their invention than the Patent Office, including information that might compromise patentability.[141] And since the Patent Office has no way to test or verify what is disclosed, it must rely on information presented by the applicant.[142] In the case of experimental failure, the applicant has a great incentive *not* to disclose such information because the Patent Office has no other way to find out about it.[143] The confluence of these factors gives rise to an information asymmetry between the Patent Office and the applicant.[144] As a result, the Patent Office and the courts impose a duty of candor and good faith (also known as the duty of disclosure)[145] upon applicants to combat the information asymmetry.

1. Basic Principles

The duty of disclosure is inextricably intertwined with the public's interest in granting patents. The essence of the U.S. patent system is a quid pro quo between the patentee and the public.[146] The basic idea is that in order to promote the full disclosure of information about the invention to the public, the patentee must receive something in return.[147] What the patentee

http://www.pnrjournal.com/; *Journal of Negative Results in Biomedicine*, http://jnrbm.biomedcentral.com/; and *New Negatives in Plant Science*, http://www.journals.elsevier.com/new-negatives-in-plant-science.

141 *Cf.* Joseph Scott Miller, *Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents*, 19 BERKELEY TECH. L.J. 667, 734 (2004) (arguing that applicants can do much to improve the information deficit because they "know better than [the Patent Office or] anyone else precisely what it is they have developed or invented.").

142 Beckman Instruments, Inc. v. Chemtronics, Inc., 439 F.2d 1369, 1378-79 (5th Cir. 1970); FTC REPORT, *supra* note 7, ch. 5, at 9 ("Yet the PTO lacks testing facilities, and assertions that cannot be overcome by documentary evidence promptly identifiable by the examiner often must be accepted.").

143 *See* Timothy R. Holbrook, *Patents, Presumptions, and Public Notice*, 86 IND. L.J. 779, 805, 818 (2011) [hereinafter Holbrook, *Presumptions*] (exploring the incentives for applicants to behave strategically and withhold certain information from the examiner, particularly in the absence of an adversarial check).

144 For a deeper discussion of the information asymmetry, see Seymore, *Patent Asymmetries*, *supra* note 15, at 991-96.

145 Digital Control, Inc. v. Charles Mach. Works, 437 F.3d 1309, 1314 (Fed. Cir. 2006) (describing the duty of candor and good faith).

146 Special Equipment Co. v. Coe, 324 U.S. 370, 378 (1945) (discussing the bestowal of exclusivity that accompanies the grant of a patent); Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480-81 (1974) (explaining the wisdom of bestowing limited monopoly rights in the patent system to encourage innovation).

147 *Kewanee*, 416 U.S. at 480-81.

gets is the limited period of exclusivity conferred by the patent grant.[148] The public gets detailed knowledge about the invention as soon as the patent document publishes[149] and possession of it at the end of the patent term.[150]

But the putative public benefit of this paradigm rests on the assumption that the applicant was honest and candid with the Patent Office.[151] Since the Patent Office lacks its own testing facilities and unlimited time to ascertain the facts necessary to evaluate the patentability of each application, it must rely on applicants to disclose most of the facts upon which its decisions are based. According the C.C.P.A., this creates a "relationship of trust" between the Patent Office and the applicant.[152] Thus, the "highest standards of honesty and candor" on the part of applicants in presenting facts to the Patent Office are not only necessary but "essential" elements in a working patent system.[153]

Similarly, the Supreme Court has recognized that in working with applicants during patent prosecution, the Patent Office "must rely on their integrity and deal with them in a spirit of trust and confidence."[154] This, according to the Court, "requires the highest degree of candor and good faith."[155] Imposing a duty of candor is appropriate because

> A patent by its very nature is affected with a public interest. As recognized by the Constitution, it is a special privilege designed to serve the public purpose of promoting the "Progress of Science and useful Arts." At the same time, a patent is an exception to the general rule against monopolies and to the right to access to a free and open market. The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope.[156]

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148 *Id.* at 480 ("In return for the right of exclusion—this 'reward for inventions'—the patent laws impose upon the inventor a requirement of disclosure." (citation omitted)).

149 *See id.* at 481 (explaining that when the information disclosed in a patent becomes publicly available it adds to the "general store of knowledge" and assumedly will stimulate ideas and promote technological development).

150 Evans v. Eaton, 20 U.S. (7 Wheat.) 356, 418 (1822) ("The object is to put the public in complete possession of the invention . . . so that interference with it may be avoided while the patent continues, and its benefits may be fully enjoyed by the public, after the patent expires.").

151 Robert J. Goldman, *Evolution of the Inequitable Conduct Defense in Patent Litigation*, 7 HARV. J.L. & TECH. 37, 37 (1993) (discussing the conflict patent attorneys face between the duty of candor to the PTO and a duty to zealously work for their clients and the negative incentives that system can cause).

152 Norton v. Curtiss, 433 F.2d 779, 793 (C.C.P.A. 1970).

153 *Id.* at 794; *cf.* Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995) (explaining that applicants must prosecute patent applications "with candor, good faith, and honesty.").

154 Kingsland v. Dorsey, 338 U.S. 318, 319 (1949).

155 *Id.*

156 Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816 (1945) (discussing the importance of the patent system to the public).

Thus, the duty not only helps ensure that the Patent Office evaluates patentability based on *all* of the relevant information known to the applicant—it also helps ensure that the public gets its end of the patent bargain.

The Patent Office imposes the duty of disclosure on every individual substantively involved in patent prosecution—including the inventor, the attorney or agent that prepares the patent application, and the assignee.[157] These individuals must "disclose to the [Patent] Office *all* information known to that individual to be material to patentability."[158] Importantly for present purposes, materiality "embraces *any* information" relevant to patentability,[159] including that pertaining to enablement.[160] Finally, the duty exists with respect to each claim in a patent application until a patent issues or the application is abandoned.[161]

2. Breach and Inequitable Conduct

The duty of disclosure is enforced primarily through the judge-made doctrine of inequitable conduct.[162] A finding of inequitable conduct renders a patent unenforceable[163] if intentional misconduct (such as a deliberate misrepresentation or omission of material information from the Patent Office) led the patentee to obtain an unwarranted patent claim.[164] The Patent Office rarely learns about potential misconduct during prosecution; it typically comes to light in patent litigation.[165] Thus, inequitable conduct is usually asserted as an equitable defense to patent infringement.[166]

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157 *See* 37 C.F.R. § 1.56(a) (2015) (setting the requirements for the duty of disclosure).

158 *Id.* (emphasis added).

159 Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 326 F.3d 1226, 1234 (Fed. Cir. 2003).

160 *Id.*; MPEP, *supra* note 57, § 2001.

161 37 C.F.R. § 1.56(a); MPEP, *supra* note 57, § 2001.04.

162 The doctrine evolved from several Supreme Court cases applying the equitable unclean hands doctrine as a defense to patent infringement. *See* Keystone Driller Co. v. General Excavator Co., 290 U.S. 240, 245 (1933); Hazel-Atlas Glass Co. v. Hartford-Empire Co., 322 U.S. 238, 249-50 (1944), *overruled on other grounds by* Standard Oil Co. v. United States, 429 U.S. 17 (1976); *see also* Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816 (1945) (defining the doctrine of inequitable conduct and tracking its progress and development).

163 Unlike invalidity which may affect a single claim, "it is . . . settled law that inequitable conduct with respect to one claim renders the *entire patent* unenforceable." Baxter Int'l, Inc. v. McGaw, Inc., 149 F.3d 1321, 1332 (Fed. Cir. 1998) (emphasis added). Moreover, "the taint of a finding of inequitable conduct can spread from a single patent to render unenforceable other related patents and applications if they are sufficiently related." Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1288-89 (Fed. Cir. 2011) (en banc) (citation omitted).

164 *Therasense*, 649 F.3d at 1292.

165 *See* Gary M. Hoffman & Michael C. Greenbaum, *The Duty of Disclosure Requirement*, 16 AIPLA Q.J. 124, 145 (1988) (discussing a process of finding fraud that relies on the examiners and leads to inequities in reporting).

166 Am. Calcar, Inc. v. Am. Honda Motor Co., 768 F.3d 1185, 1188 (Fed. Cir. 2014); *see also* 6A CHISUM, *supra* note 69, § 19.03.

The Federal Circuit recently reconsidered the contours and standards governing the inequitable conduct defense in *Therasense, Inc. v. Becton, Dickinson and Co*.[167] The defense has two prongs—materiality and intent.[168] Regarding materiality, the general rule is that the misrepresented or omitted information must be "but-for material"—meaning that the challenger must prove, by a preponderance of the evidence, that "the [Patent Office] would not have allowed a claim had it been aware of the undisclosed" information.[169] Regarding intent, the challenger must prove by clear and convincing evidence a specific intent to deceive the Patent Office.[170] In the case of nondisclosure, this requires proof that "the applicant made a deliberate decision to withhold" known material information.[171] This means that the applicant "knew of the [information], knew that it was material, and made a deliberate decision to withhold it."[172] If the challenger proves both elements, then the court "must weigh the equities to determine whether the applicant's conduct before the [Patent Office] warrants rendering the entire patent unenforceable."[173]

3. Submitting Misleading Technical Information

Although the Patent Office does not explicitly address failure in its materials on the duty of disclosure, it provides guidance on filing patent applications with technical inaccuracies. In a section entitled "Aids to Compliance with Duty of Disclosure,"[174] the *Manual of Patent Examining Procedure*[175] cautions applicants that "[c]are should be taken to see that inaccurate statements or inaccurate experiments are not introduced into the [patent document], either inadvertently or intentionally."[176]

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167 649 F.3d at 1276.

168 *Id.* at 1290.

169 *Id.* at 1291; *accord* Aventis Pharma S.A. v. Hospira, Inc., 675 F.3d 1324, 1334 (Fed. Cir. 2012). The key exception is in cases of "affirmative acts of egregious misconduct" such as when the patentee filed "an unmistakably false affidavit." *Therasense*, 649 F.3d at 1292.

170 *Therasense*, 649 F.3d at 1290.

171 *Id.*

172 *Id.*; *accord* 1st Media, LLC v. Electronic Arts, Inc., 694 F.3d 1367, 1376-77 (Fed. Cir. 2012) (affirming the *Therasense* three-part test for deceptive intent). Given the difficulty in obtaining direct evidence of deceptive intent, the intent to deceive can be inferred from indirect and circumstantial evidence if it is "the single most reasonable inference." *Therasense*, 649 F.3d at 1290 (citation omitted).

173 *Therasense*, 649 F.3d at 1287.

174 MPEP, *supra* note 57, § 2004.

175 The *Manual of Patent Examining Procedure* (MPEP) provides guidance to patent examiners and is entitled to judicial notice as the Patent Office's official interpretation of statutes and regulations. Molins PLC v. Textron, Inc., 48 F.3d 1172, 1180 n.10 (Fed. Cir. 1995); *see also supra* note 57. The MPEP "is also made available to patent applicants and their lawyers as well as to the general public . . . [and] is used frequently by patent lawyers and agents in advising applicants and in preparing their various papers for filing in the Patent Office." *In re* Kaghan, 387 F.2d 398, 401 (C.C.P.A. 1967).

176 MPEP, *supra* note 57, § 2004.

Concealing failure would qualify as an intentional disclosure of an inaccurate statement or experiment. If a patent applicant files a patent application with a prophetic disclosure and then learns (through post-filing experimentation) that some of the subject matter does not work as described, the written description would be inaccurate and the claims would cover inoperative embodiments. This, of course, raises an enablement issue.[177] If the applicant does nothing, the key question is whether the concealment constitutes inequitable conduct.

Deliberately concealing experimental failure could be viewed as an attempt to mislead the Patent Office into granting the patent. This could easily meet the *Therasense* standard for inequitable conduct.[178] To illustrate, I return to the hypothetical introduced earlier.[179] Recall that the inventor disclosed and claimed four compounds *W*, *X*, *Y*, and *Z* that were purportedly effective for treating arthritis. Recall that *W* had been made and showed promising results but the others had been disclosed prophetically. Post-filing experimentation revealed that *X* works as described but *Y* and *Z* do not. Nondisclosed information is but-for material if the Patent Office "would not have allowed a claim had it been aware of it."[180] This prong is satisfied here because an examiner probably would have rejected the claim because *Y* and *Z* are nonenabled.[181] For intent, the question is whether the applicant "knew of the [information], knew that it was material, and made a deliberate decision to withhold it."[182] This prong could be satisfied if the applicant knew that the experimental failure would create an enablement problem and decided to deliberately conceal this information from the Patent Office.

The Federal Circuit has had occasion to consider alleged inequitable conduct where the patentee withheld information material to enablement. In *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer Inc.*,[183] a patent was held unenforceable because the patentee intentionally failed to disclose that some of the claimed subject matter did not work.[184] To simplify the facts, the inventors had drafted a scientific article which disclosed a synthetic process

177 *See supra* Part I.C.

178 *See supra* notes 167–173 and accompanying text.

179 *See* INTRODUCTION, *supra*.

180 Am. Calcar, Inc. v. Am. Honda Motor Co., 768 F.3d 1185, 1189 (Fed. Cir. 2014) (internal citation and quotation marks omitted).

181 This admittedly is a close question. *Compare* Atlas Powder Co. v. E.I. Du Pont de Nemours & Co., 750 F.2d 1569, 1576 (Fed. Cir. 1984) (explaining that a claim is not necessarily invalid for nonenablement if some of the claimed embodiments are inoperative) *with In re* Cook, 439 F.2d 730, 735 (C.C.P.A. 1971) (explaining that a claim might be invalid for nonenablement if it covers a significant number of inoperative embodiments).

182 Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1290 (Fed. Cir. 2011) (en banc).

183 326 F.3d 1226 (Fed. Cir. 2003).

184 *Id.* at 1239-40.

for making the cancer drug Taxol but noted that two chemical reactants, when used in the process, did not work.[185] The inventors sent the draft to their French patent agent, who prepared a French patent application that disclosed and claimed the two chemicals as permissible reactants in the process.[186] The French application was filed, the scientific article published, and a counterpart U.S. application filed.[187] The scientific article was not disclosed to the examiner during prosecution.[188] The U.S. application ultimately issued as a patent.[189] Because the patentee wanted more claim coverage, it filed a reissue application which was assigned to the same examiner.[190] The attorney handling the reissue disclosed the scientific article late in the prosecution, which the examiner considered.[191] The patent eventually reissued.[192]

The Federal Circuit affirmed the district court's conclusion that inequitable conduct had occurred.[193] The scientific article was material because it disclosed information about enablement—the article taught that two chemical reactants in the claimed process would not work.[194] And no testimony from the inventors or expert witnesses indicated that the failures reported in the article were limited to a single experiment or that a PHOSITA could figure out how to make the claimed process work with the two reactants at issue without undue experimentation.[195] Intent was satisfied because the patent agent intentionally withheld the scientific article in an attempt to mislead the Patent Office during the original prosecution. The court rejected the argument that intent was lacking because the inventors believed that the application was sufficiently enabling; the relevant inquiry was the applicant's intent with respect to *nondisclosure* of relevant information.[196] That the

185 *Id.* at 1230.

186 *See id.* at 1230-31.

187 *Id.* Applicants who first file abroad can obtain the benefit of the foreign filing date for the corresponding U.S. application if certain conditions are met. *See* 35 U.S.C. § 119(a) (2012).

188 *Bristol-Myers Squibb*, 326 F.3d at 1231.

189 *Id.*

190 Under certain circumstances, after a patent issues, the patentee can withdraw the issued patent and subject it to further prosecution through a reissue process if the patent is deemed defective. 35 U.S.C. § 251. One basis for reissue can be that the patentee "claim[ed] more or less than he had a right to claim in the patent." 35 U.S.C. § 251(a). In *Bristol-Myers Squibb*, the patentee filed the reissue patent application to obtain coverage for previously disclosed but unclaimed subject matter. 326 F.3d at 1232.

191 *Bristol-Myers Squibb*, 326 F.3d at 1233.

192 *Id.*

193 *Id.* at 1229.

194 In this pre-*Therasense* case the court applied the "reasonable examiner" materiality standard. *Id.* at 1234. Under that standard, materiality "embraces *any* information that a reasonable examiner would be substantially likely to consider important in deciding whether to allow an application to issue as a patent." GFI, Inc. v. Franklin Corp., 265 F.3d 1268, 1274 (Fed. Cir. 2001).

195 *Bristol-Myers Squibb*, 326 F.3d at 1235.

196 *Id.* at 1241.

scientific article was subsequently disclosed in the reissue prosecution did not cure the inequitable conduct because it should have been disclosed sooner.[197]

Very important for present purposes, the Federal Circuit affirmed the district court's finding that the patent agent intentionally drafted the claims more broadly than warranted by the scientific evidence.[198] The patent agent withheld the scientific article because disclosing information that two of the claimed reactants did not work would have raised an enablement issue and led the examiner to insist on narrower claims. In sum, the applicant's failure to disclose information relevant to enablement led the Patent Office to grant a patent of unwarranted scope.[199]

B. *The "Inoperative Embodiments" Doctrine*

Patent applicants take the duty of disclosure seriously given the potential consequences for noncompliance.[200] While applicants are well-advised to disclose in the case of doubt,[201] no action is required if the information is not material to patentability. In the case of inventive failure, if the examiner would have allowed the claim notwithstanding knowledge that the claim encompasses nonenabled subject matter, then silence will not breach the duty of disclosure. Some would argue that the "inoperative embodiments" doctrine, discussed below, permits concealment without committing inequitable conduct.

1. Contours

Since all would agree that a valid patent claim should not cover subject matter that does not work,[202] one may wonder why such claims proliferate.

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197 *Id.* at 1237. Reissue cannot be used to cure inequitable conduct that occurred during the original prosecution. Aventis Pharma S.A. v. Amphastar Pharm., Inc., 525 F.3d 1334, 1341 n.6 (Fed. Cir. 2008). Indeed, the (reissue) patent might be valid but still rendered unenforceable due to inequitable conduct. *See* PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc., 225 F.3d 1315, 1322 (Fed. Cir. 2000).

198 *Bristol-Myers Squibb*, 326 F.3d at 1239.

199 *Id.* at 1235.

200 Aside from rendering the patent or patent family unenforceable, a finding of inequitable conduct can "spawn antitrust and unfair competition claims," "lead[] to an award of attorney's fees," and "prove the crime or fraud exception to the attorney–client privilege." Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1289 (Fed. Cir. 2011) (en banc). It may also "paint the patentee as a bad actor" and create "ruinous consequences for the reputation of [the] patent attorney." *Id.* at 1288.

201 MPEP, *supra* note 57, § 2004.10 ("When in doubt, it is desirable and safest to submit information. Even though the attorney, agent, or applicant doesn't consider it necessarily material, someone else may see it differently . . . ."); LaBounty Mfg., Inc. v. United States Int'l Trade Comm'n, 958 F.2d 1066, 1076 (Fed. Cir. 1992) ("Close cases should be resolved by disclosure, not unilaterally by the applicant.").

202 Long ago there was a rule applied by some courts that "a claim which covers an inoperative form along with operative forms [of the invention] is void." Karl B. Lutz, *Evolution of the Claims of U.S. Patents*, 20 J. PAT. OFF. SOC'Y 377, 398 (1938).

Recall that enablement is a standard which affords the decisionmaker a fair amount of discretion. Thus, the decisionmaker can set the *threshold* for enablement sufficiently high to render *any* claim covering nonenabled subject matter invalid. Indeed, there are plenty of old cases where the court has struck down a broad claim that covered inoperable embodiments within its scope.[203] And recently the Federal Circuit has been touting a "full scope" enablement requirement,[204] meaning that "[c]laims are not enabled when, at the effective filing date of the patent, [a PHOSITA] could not practice their *full scope* without undue experimentation."[205] In simple terms, this means that the patent's written description "must enable every potential embodiment of the invention."[206] So it might seem that the rise of full scope enablement would eventually solve the failure problem.[207]

But the story is not so simple. There is an enablement subdoctrine—the *inoperative embodiments doctrine*[208]—which renders a broad claim not necessarily invalid as long as some (perhaps most) of the subject matter works as described.[209] The analysis will depend on the circumstances of each case—including the nature of the subject matter,[210] the PHOSITA's level of skill,[211] and the number of inoperative embodiments.[212]

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203 *See, e.g.*, Incandescent Lamp Patent, 159 U.S. 465, 474 (1895); *see also* Corona Cord Tire Co. v. Dovan Chem. Corp., 276 U.S. 358, 388 (1928).

204 Sitrick v. Dreamworks, LLC, 516 F.3d 993, 999 (Fed. Cir. 2008).

205 Wyeth & Cordis Corp. v. Abbott Labs., 720 F.3d 1380, 1384 (Fed. Cir. 2013) (emphasis added) (citing MagSil Corp. v. Hitachi Glob. Storage Techs., Inc., 687 F.3d 1377, 1380-81 (Fed. Cir. 2012)).

206 Sherkow, *supra* note 95, at 875.

207 *See* Sean B. Seymore, *The Enablement Pendulum Swings Back*, 6 NW. J. TECH. & INTELL. PROP. 278, 284-89 (2008) (describing the emergence of "full scope" enablement as a "lever to invalidate patents"); *cf.* James Farrand et al., *"Reform" Arrives in Patent Enforcement: The Big Picture*, 51 IDEA 357, 415-17 (2011) (describing the full scope enablement doctrine and noting that it "can invalidate many existing broad patent claims, particularly if it continues to be applied as broadly as it is being stated.").

208 The doctrine has existed for quite some time. *See* RIDSDALE ELLIS, PATENT CLAIMS §§ 216-226 (1949); H. Einhorn, *The Enforceability of Patent Claims Encompassing Some Inoperative Species*, 45 J. PAT. OFF. SOC'Y 716, 716-19 (1963); Herbert H. Goodman, *The Invalidation of Generic Claims by Inclusion of a Small Number of Inoperative Species*, 40 J. PAT. OFF. SOC'Y 745, 748-50 (1958). Professor Jeffrey Leftsin named it the "inoperative embodiments doctrine" in Jeffrey A. Leftsin, *The Formal Structure of Patent Law and the Limits of Enablement*, 23 BERKELEY TECH. L.J. 1141, 1178 (2008).

209 *See In re* Cook, 439 F.2d 730, 735 (C.C.P.A. 1971); *In re* Sarett, 327 F.2d 1005, 1019 (C.C.P.A. 1964) (noting that the mere inclusion of inoperative embodiments in a claim will not defeat patentability).

210 Until recently, the amount of enablement required to enable a broad claim turned on whether the claimed subject matter was from a "predictable" or "unpredictable" field. *See* discussion *supra* notes 49–55 and *infra* notes 243–247 and accompanying text.

211 *See, e.g.*, *In re* Cook, 439 F.2d at 735 (upholding a broad claim that read on a large number of inoperative embodiments because a PHOSITA could figure out with minimal effort which of the unmade embodiments could work as intended).

212 *See, e.g.*, Incandescent Lamp Patent, 159 U.S. 465, 474 (1895) (determining that the claim was invalid because most of the claimed embodiments were inoperable); Atlas Powder Co. v. E.I. Du Pont de Nemours & Co., 750 F.2d 1569, 1576-77 (Fed. Cir. 1984) ("[I]f the number of inoperative

The inoperable embodiments doctrine is quite patentee-friendly.[213] The courts make clear that "[i]t is not a function of the claims to specifically exclude . . . possible inoperative substances."[214] If the applicant had to demonstrate that every claimed embodiment works, according to the courts, "the research to do this would evidently be endless."[215] So the traditional evidentiary rules apply; most notably, a presumption in both the Patent Office and the courts that the full scope of a claim is enabled.[216] The burden rests with the party challenging enablement to prove unpatentability or invalidity, respectively.[217]

Yet despite the evidentiary rules, the older cases limited the applicability of the doctrine in patent prosecution. In *In re Cook*,[218] the C.C.P.A. had to consider the patentability of a broad claim which covered inoperative subject matter.[219] Writing for the court, Judge Giles Rich (the co-drafter of the 1952 Patent Act and regarded by many as "the founding father of modern patent law"[220]) explained that when the examiner makes a prima facie case of inoperability, "it becomes incumbent upon the applicant either to reasonably limit his claims to the approximate area where operativeness has not been challenged or to rebut the examiner's challenge either by the submission of representative evidence . . . or by persuasive arguments based on known laws

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[embodiments] becomes significant, and in effect forces [a PHOSITA] to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid."); *see also* Durel Corp. v. Osram Sylvania Inc., 256 F.3d 1298, 1306-07 (Fed. Cir. 2001) (determining that if the accused infringer shows that a "significant percentage" of embodiments encompassed by the claims are inoperable, that might be sufficient to prove invalidity).

213 *See* ELLIS, *supra* note 208, § 217 ("One thing seems clear and that is that usually 100% operativeness is not required.").

214 *In re* Dinh-Nguyen, 492 F.2d 856, 858-59 (C.C.P.A. 1974), *quoted in Atlas Powder*, 750 F.2d at 1576.

215 *In re Sarett*, 327 F.2d 1005, 1019 (C.C.P.A. 1964); *see also* ELLIS, *supra* note 208, § 214 (recognizing that in theory the only way that a chemist can determine if all species within a claimed genus will work as described is by testing "at least a majority of the members of that genus").

216 *See In re* Marzocchi, 439 F.2d 220, 223 (C.C.P.A. 1971) (explaining the presumption and placing the burden on the examiner to prove nonenablement by a preponderance of the evidence); ELLIS, *supra* note 208, § 227 ("[U]nless the examiner has good reason for doubting the applicant's statements, he should accept them at face value."); *cf. In re* Ellis, 37 App. D.C. 203, 209 (D.C. Cir.) (1911) (reaffirming the rule that doubts as to operability of all of the claimed subject matter in a claimed genus should be resolved in the applicant's favor). *But see In re* Harwood, 390 F.2d 985, 989-90 (C.C.P.A. 1968) (affirming a § 112 rejection for an application claiming a genus of compounds as useful as a pesticide because the Patent Office successfully proved that the claims were broader than the supporting disclosure which suggested that only certain species would work).

217 *See supra* note 216; *see also* PPG Industries, Inc. v. Guardian Industries Corp., 75 F.3d 1558, 1564 (Fed. Cir. 1996) (holding that a patented invention was enabled because the challenger did not prove that undue experimentation would be required to practice the undescribed embodiments).

218 439 F.2d 730 (C.C.P.A. 1971).

219 *Id.* at 731-32.

220 KIEFF, *supra* note 22, at 24. Judge Rich joined the C.C.P.A. in 1956 and later served on the Federal Circuit until his death in 1999 at age 95. *Id.*

of physics and chemistry."[221] Importantly, he felt that in patent prosecution, the applicant still has a chance to amend the claims.[222] Of course, this is not the case in litigation. In that context Judge Rich thought that the doctrine can be justified because equitable considerations might be present;[223] namely, the court's reluctance to permit an infringer to raise an invalidity defense merely because one or more claimed embodiments do not work.[224]

Nonetheless, the inoperative embodiments doctrine vitiates full scope enablement. Again, full scope enablement means that a PHOSITA should be able to read the patent's written description of the invention and—combined with the PHOSITA's own knowledge and skill—make and use *everything* that is claimed. So if the patent covers a billion chemical compounds which purportedly have a specific pharmacological activity, the PHOSITA should be enabled to make and use *each of them*.[225]

2. Theoretical Rationale

Although the doctrine's existence essentially guarantees the issuance of patents that claim failure, it finds considerable support in patent law. Robert Merges and Richard Nelson argue that requiring a tighter connection between the disclosure and the claims would lead to narrow patents of little value because an imitator could find minor variations over the embodiments specifically exemplified or actually reduced to practice.[226]

To better understand this reasoning, consider the following scenario, which is pretty typical in unpredictable fields:[227]

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221 *In re Cook*, 439 F.2d at 734-35 n.4 (citation omitted).

222 *Id.* at 734 n.3; *cf.* ELLIS, *supra* note 208, § 218 (explaining that when claims are obviously too broad, "the Patent Office should require their limitation, where possible, so that the obviously inoperative members of the class are excluded.").

223 *Cook*, 439 F.2d at 734 n.4. (citing Einhorn, *supra* note 208; Goodman, *supra* note 208).

224 *See* ELLIS, *supra* note 208, § 216 ("If most of the members of the class are operative and a later comer wishes to use one of such members, he should not be permitted to excuse his infringement of a broad claim to the class by a diligent search for some member or members which will not work.").

225 This normative position aligns with that of the author of an old patent treatise:

> A chemist tests a substance X and finds it useful for his purpose. He then makes a guess that all other substances of the same chemical class will act in the same way. If his guess is wrong, his broad claim to the entire class is invalid . . . . All that the inventor did was to discover that species X would work. His broad claim to the entire genus was nothing more than a pregnant surmise or a promising hypothesis. If he guesses right, the patent will be valid.

Id. § 221 (internal citation and quotation marks omitted).

226 Merges & Nelson, *supra* note 74, at 845; *see also* Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052, 1071 (Fed. Cir. 2005) (arguing that narrow patent rights become worthless as new modes of practicing the invention develop).

227 See *supra* notes 49–55 and accompanying text for a discussion of the unpredictable arts.

> A discovery is made that a chemical has certain properties and utility . . . . The inventor, a skilled chemist, predicts that all or most of the other members of the class have the same properties and utility. Further experimentation . . . reveals that other representative chemicals within the class do have these properties and utility. On the basis of the foregoing, the inventor believes that all members of the class should be operative. As a careful chemist, he admits the possibility that some members may exhibit anomalous behavior. The only method of determining whether a given chemical is operative is to test it. The class usually includes thousands of known and theoretical compounds. The cost of testing them all would be prohibitive.
>
> To claim the invention broadly, it is necessary to claim the *entire class*. To claim less than the entire class allows the patent to be avoided . . . .[228]

Thus, the doctrine seemingly adds value to patent claims.[229] Infringers cannot point to the inoperability of one (or more) species as a basis for invalidating a broad claim.[230]

Another rationale for the inoperable embodiments doctrine is that a more stringent enablement requirement would contravene § 112, particularly in the unpredictable arts. The C.C.P.A. explained this rationale in *In re Angstadt*.[231] The applicant claimed a genus of thousands of compounds of similar chemical structure that were useful as catalysts for forming hydroperoxides.[232] The written description disclosed that forty experiments had been carried out and revealed that some of the claimed compounds failed to work as described—meaning that they were inoperable as catalysts.[233] And since the applicant did not specify how to figure out which compounds were (in)operable, the Patent Office rejected the

228 Goodman, *supra* note 208, at 745 (emphasis added).

229 It is true that claims are of little value unless they can ensnare or deter a potential infringer. Patentees achieve this goal by obtaining broad claims which cover "all expected and unanticipated [variants] that competitors and others may later develop and all intentional and unintentional copies of the claimed invention which embody the inventor's concept." ROBERT C. FABER, LANDIS ON MECHANICS OF PATENT CLAIM DRAFTING § 10:1.1[B] (5th ed. 2004). Thus, the claims must cover not only competing products envisioned at the time of filing, but also competing products that the patentee could barely imagine which employ the concept of the invention. *See id.*; George F. Wheeler, *Creative Claim Drafting: Claim Drafting Strategies, Specification Preparation, and Prosecution Tactics*, 3 J. MARSHALL REV. INTELL. PROP. L. 34, 38-40 (2003) ("If a patentee wants the best available protection, the retained patent prosecutor must do the work of discovering the available protection in view of the hprior art and obtaining the broadest possible claims to literally cover the invention and reasonably foreseeable variants.").

230 Einhorn, *supra* note 208, at 718.

231 537 F.2d 498 (C.C.P.A. 1976).

232 *Id.* at 500.

233 *Id.*

claims for nonenablement because a PHOSITA would have to engage in undue experimentation to do so.[234] On appeal, the C.C.P.A. reversed:

> Appellants have apparently not disclosed every catalyst which will work; they have apparently not disclosed every catalyst which will not work. The question, then, is whether in an unpredictable art, section 112 requires disclosure of a test with every species covered by a claim. To require such a complete disclosure would apparently necessitate a patent application or applications with "thousands" of examples or the disclosure of "thousands" of catalysts along with information as to whether each exhibits catalytic behavior . . . . More importantly, such a requirement would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments. This would tend to discourage inventors from filing patent applications in an unpredictable area since the patent claims would have to be limited to those embodiments which are expressly disclosed.[235]

Thus, according to this view, the doctrine promotes early disclosure,[236] gives the patentee an edge over competitors,[237] and prevents patent documents from becoming overly thick.[238]

Finally, ratcheting up the enablement threshold to exclude inoperable embodiments would render an incalculable number of patents technically invalid for nonenablement—particularly in the unpredictable fields.[239] Such

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234 *Id.* at 501.

235 *Id.* at 502-03.

236 As stated by one court:

> The invention . . . was a generic invention . . . . Rohm and Haas was not required to limit its 1958 application to the precise crops where selectivity had at that time been demonstrated. Such a requirement would discourage an inventor from disclosing and teaching his discovery for the public's benefit until all screening had been completed, in contravention to the guiding principles underlying § 112.

Rohm & Haas Co. v. Dawson Chemical Co., Inc., 557 F. Supp. 739, 801-02 (S.D. Tex. 1983), *rev'd on other grounds*, 722 F.2d 1556 (Fed. Cir. 1983).

237 *See* Edlyn S. Simmons, *Prior Art Searching in the Preparation of Pharmaceutical Patent Applications*, 3 DRUG DISCOVERY TODAY 52, 52 (1998) (explaining the importance of drafting broad generic claims which include hypothetical compounds in order to prevent competitors from developing them).

238 *See In re* Gay, 309 F.2d 769, 774 (C.C.P.A. 1962) ("Not every last detail is to be described, else patent specifications would turn into production specifications, which they were never intended to be. United States specifications have often been criticized as too cluttered with details to give an easy understanding of what the invention really is."). Under current Patent Office practice, applicants must pay additional filing fees for applications which exceed a threshold page count. *See* 35 U.S.C. § 41(a)(1)(G) (2012).

239 Bernard Chao argues that a heightened enablement standard would be inequitable: "There is always an unforeseen embodiment that falls within a claim. In many cases, that embodiment will not be enabled. But a claim should not be invalidated simply because the inventor did not foresee every embodiment that may eventually fall within its scope." Bernard Chao, *The Infringement Continuum*, 35 CARDOZO L. REV. 1359, 1378 (2014).

action could immediately place the patent portfolios of numerous companies at risk and open the door for more enablement challenges in patent litigation.[240] But there is another side to the story. Abandoning the doctrine and insisting on full scope enablement would lead to better claim drafting, narrower claims, and—importantly for present purposes—fewer issued patents that claim failure.[241]

3. Robustness

As discussed above, it is hard to reconcile the inoperative embodiments doctrine with full scope enablement. A claim is either enabled across its full scope or it is not. Given the Federal Circuit's move toward full scope enablement, this raises the question about the continued viability of the inoperative embodiments doctrine.

There are two reasons why the inoperative embodiments doctrine is arguably less robust than before. First, the court has eviscerated the *single embodiment doctrine*—a related doctrine which also preserved the validity of a dubiously enabled claim.[242] Until recently, there was a dichotomy in enablement jurisprudence:[243] the courts applied separate enablement standards for inventions in the predictable and unpredictable arts.[244] In the predictable arts, which includes electrical and mechanical devices, a specific and detailed teaching was not required because the inventions are rooted in well-defined, predictable factors.[245] This meant that an applicant rarely needed to show more than a single embodiment to enable a broad claim.[246]

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240 A similar concern arose in the wake of several biotech-related Supreme Court decisions that narrowed the scope of patentable subject matter under 35 U.S.C. § 101. *See, e.g.*, Mayo Collaborative Svcs. v. Prometheus Labs., Inc., 566 U.S. 66, 72-73 (2012) (holding that a method for determining the amount of a drug for treating a patient was unpatentable under § 101 for encompassing a law of nature); *see also, e.g.*, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2111 (2013) (holding that isolated DNA fragments are unpatentable products of nature). But such fears have not been realized. *See, e.g.*, Joseph F. Aceto, *Patent Portfolios After* Myriad*, How to Fit in Those New Genes?*, 4 AM. CHEMICAL SOC'Y MED. CHEMISTRY LETTERS 681, 682 (2013) (explaining why "the sky is not falling").

241 And as discussed *infra* Part IV, such a move could open the door for new inventors who would no longer have to work in the shadow of (invalid) broad claims. *See also* discussion *infra* Section III.A.

242 For a general discussion of the doctrine, see Seymore, *Heightened Enablement*, *supra* note 61, at 136-37; Seymore, *Enablement Pendulum*, *supra* note 207, at 280-84.

243 For a deeper discussion of the predictable–unpredictable dichotomy, see Seymore, *Heightened Enablement*, *supra* note 61, at 136-39; Seymore, *Enablement Pendulum*, *supra* note 207, at 282-84.

244 See *supra* notes 49-55 and accompanying text for a discussion of the unpredictable arts.

245 *See In re* Vaeck, 947 F.2d 488, 496 (Fed. Cir. 1991) (noting that the requisite level of disclosure for an invention involving predictable mechanical or electrical elements is less than that required for the unpredictable arts).

246 The patentee is "generally allowed [broad] claims, when the art permits, which cover more than the specific embodiment shown." *In re* Vickers, 141 F.2d 522, 525 (C.C.P.A. 1944); *id.* at 527 ("In mechanical cases . . . broad claims may be supported by a single form of the apparatus disclosed in an

The broad claim survived even if it encompassed inadequately disclosed subject matter because applicants in predictable technologies could always rely on the PHOSITA's knowledge to fill in information gaps omitted from the disclosure.[247] But in recent years the dichotomy has disappeared; the Federal Circuit has vitiated the "single embodiment" enablement doctrine and adopted a unitary (and more stringent) "full scope" enablement standard.[248] This is perhaps a judicial effort to reform the patent system by making patents harder to obtain and easier to invalidate.[249]

Second and relatedly, full scope enablement is itself a heightened standard than what was previously applied.[250] Now the Federal Circuit is willing to invalidate patents that previously would have survived an enablement challenge. So, a case like *Angstadt*[251]—where a disclosure describing a handful of compounds actually tested is purported to enabled a broad claim covering thousands or millions of embodiments—might come out differently today.[252]

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applicant's application."); *see also* Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1533 (Fed. Cir. 1987) (holding that a patent need only disclose a single embodiment to satisfy enablement).

247 *In re* Fisher, 427 F.2d 833, 839 (C.C.P.A. 1970) ("In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws."), *quoted in* Cedarapids, Inc. v. Nordberg, Inc., No. 95-1529, 1997 WL 452801, at *2 (Fed. Cir. Aug. 11, 1997).

248 *See, e.g.*, Sitrick v. Dreamworks, LLC, 516 F.3d 993, 1000-03 (Fed. Cir. 2008) (determining that a disclosure which enabled video games did not support a broad claim that covered movies as well as video games); Auto. Tech. Int'l, Inc. v. BMW, 501 F.3d 1274, 1283-85 (Fed. Cir. 2007) (determining that a disclosure which enabled mechanical side-impact sensors was insufficient to support a broad claim encompassing both mechanical and electronic sensors because the two were "distinctively different"); Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371, 1379-80 (Fed. Cir. 2007) (determining that a disclosure which enabled an injector with a pressure jacket was insufficient to support a claim that covered injectors both with and without a pressure jacket); AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1244 (Fed. Cir. 2003) (determining that when the claims covered a Type 1 or a Type 2 aluminum coating, yet the patent only described a Type 2 coating, the claims were nonenabled because a PHOSITA could not fill in the gaps without undue experimentation).

249 JAFFE & LERNER, *supra* note 1, at 175.

250 *See* Dennis Crouch, *The New Law of Enablement*, PATENTLY-O (Mar. 22, 2007), http://patentlyo.com/patent/2007/03/the_new_law_of_.html [https://perma.cc/8REP-B3UZ] ("[The question in Liebel] is an important question because most patent claims are written to literally cover embodiments that are not fully enabled."); Dennis Crouch, *CAFC Continues to Expand Doctrine of Full Scope Enablement*, PATENTLY-O (Feb. 4, 2008), http://patentlyo.com/patent/2008/02/enablement-cont.html [https://perma.cc/2L9A-4GGK] ("The 'full scope' doctrine has recently been applied by the Federal Circuit to invalidate several patents.").

251 *See supra* text accompanying notes 231–236 (discussing the Angstadt court's concern that too high an enablement standard would require an inordinate amount of disclosure, thereby discouraging patent filing in the unpredictable arts).

252 *See, e.g.*, Wyeth and Cordis Corp. v. Abbott Labs., 720 F.3d 1380, 1385-86 (Fed. Cir. 2013) (determining that "there is no genuine dispute that practicing the full scope of the claims, measured at the time of filing, would require excessive experimentation" because the written description "disclose[d] only a starting point for further iterative research in an unpredictable and poorly understood field"); *see also* Promega Corp. v. Life Techs. Corp., 773 F.3d 1338, 1348-49 (Fed. Cir.

As noted by one commentator, "the Federal Circuit [has] aligned itself to the rule that broad claim scope requires broad disclosure."[253]

The Federal Circuit's move toward full scope enablement means that what would not have been an enablement issue in the past might be one now. So, there should be less doubt that knowledge of inventive failure that comes to light during patent prosecution—in light of the heightened enablement standard—is material to patentability. And as I discuss in the next Part, this knowledge requires action.

IV. CLAIMING AROUND FAILURE

Recall that an applicant has a duty to disclose any information that is material to patentability of one or more pending claims in a patent application.[254] The duty to disclose "exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned."[255] *Bristol-Myers Squibb* makes clear that information about (non)enablement is material to patentability.[256] Thus, I contend that an applicant that learns post-filing that (some of) the claimed subject matter does not work as described must, *at a minimum*, amend the claims to avoid inequitable conduct.[257]

2014) (noting that, as in *Wyeth*, "the claims at issue here similarly cover potentially thousands of undisclosed embodiments in an unpredictable field" but the written description only provides a "starting point" for the PHOSITA).

253 Dennis Crouch, *Federal Circuit Begins its Campaign for Patent Clarity*, PATENTLY-O (June 26, 2013), http://patentlyo.com/patent/2013/06/federal-circuit-begins-its-campaign-for-patent-clarity.html [https://perma.cc/U38B-DNQE].

254 *See* discussion *supra* subsection III.A.1.

255 37 C.F.R. § 1.56(a) (2015).

256 *See* MPEP, *supra* note 57, § 2001.04 (citing Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 326 F.3d 1226, 1234 (Fed. Cir. 2003)).

257 *See supra* subsection III.A.3. This Article focuses on *known* failure that comes to light *after* filing. If *doubts* about enablement arise *before* filing, one commentator provides advice:

> The claims should not be written so broadly as to include nonenabled subject matter . . . . If it is questionable whether anything within a broad claim would actually work in the invention, it is advisable to break up the claim into two claims, one of which is limited to operable and enabled subject matter, and the other of which is limited to [subject matter] which the inventor is not sure will actually function.

JEFFREY G. SHELDON, HOW TO WRITE A PATENT APPLICATION 6-78 (2005); *see also* ELLIS, *supra* note 208, § 226 (advocating a similar strategy). The idea is that the narrow, enabled claim will pass scrutiny by the Patent Office and survive an invalidity attack on enablement grounds. SHELDON, *supra*, at 6-77; Einhorn, *supra* note 208, at 717-18.

A. *Simple Claims*

To illustrate an amendment involving simple claims, consider again the hypothetical introduced earlier.[258] Recall that the inventor disclosed and claimed four compounds *W*, *X*, *Y*, and *Z* that were purportedly effective for treating arthritis. Recall that *W* had been made before filing and showed promising results but the others had been disclosed prophetically.[259] Suppose the inventor filed the patent application with the following claims:

1. *W*.

2. *X*.

3. *Y*.

4. *Z*.

5. A method of treating arthritis comprising administering to a patient a therapeutically effective amount of *W*.

6. A method of treating arthritis comprising administering to a patient a therapeutically effective amount of *X*.

7. A method of treating arthritis comprising administering to a patient a therapeutically effective amount of *Y*.

8. A method of treating arthritis comprising administering to a patient a therapeutically effective amount of *Z*.

This claim drafting strategy is fairly typical.[260] Note that the claim matrix includes "composition of matter" claims directed to the compounds themselves (claims 1-4) as well as (2) "method" claims directed to ways of using the compounds to treat arthritis (claims 5-8).[261]

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258 *See supra* text accompanying notes 21-24.

259 *See supra* Section I.B (discussing prophetic disclosures).

260 Often the applicant will consider claiming the thing, how to make the thing, and how to use the thing. SHELDON, *supra* note 257, at 6-77.

261 There are two principal reasons why a "composition of matter" claim covering the compound itself tends to be more valuable than those directed to a specific "method of making" or "method of using" the compound. First, the former affords the broadest protection. As Harold Wegner explains,

> [Composition of matter claims covering the compound] have always been the premium form of patent protection in the chemical industry . . . . A claim to the compound, per se, dominates every method of making that compound and every single use of that compound, every single mixture of different components that includes that compound, and every end use composition inclusive of the compound.

HAROLD C. WEGNER, PATENT LAW IN BIOTECHNOLOGY, CHEMICALS, AND PHARMACEUTICALS § 260, at 301; *see also In re* Papesch, 315 F.2d 381, 391 (C.C.P.A. 1963) (discussing the "well-recognized advantages" of composition-of-matter claims); MARTIN A. VOET, THE GENERIC CHALLENGE: UNDERSTANDING PATENTS, FDA & PHARMACEUTICAL LIFE-CYCLE

Recall that post-filing experimentation reveals that *X* works as described but *Y* and *Z* do not. Thus, the claims directed at *Y* and *Z*—claims 3, 4, 7, and 8—are nonenabled. Since nonenablement is material to patentability, the claims cannot stand as originally filed—the applicant must amend them.

The type of amendment required depends on how the original claims were drafted. The only option available for the foregoing claim matrix is cancellation—striking the nonenabled claims from the application. Thus, the examiner would only consider the patentability of claims 1, 2, 5, and 6.

B. *Complex Claims*

Complex claims are those which cover multiple embodiments of the invention. If these embodiments share a common attribute, the applicant is allowed to claim the invention with generic language. Generic claims abound in patents.[262] Below, I explain how they should be handled when post-filing experimentation reveals that one or more embodiments do not work.

For a simple illustration, consider the following hypothetical. Suppose the inventor develops a wood cleaner made from a solution of lemon oil, mineral oil, and white vinegar in a 1:1:4 ratio. Testing reveals that the solution cleans all wood surfaces including antiques, furniture, and kitchen cabinets without drying the wood finish. Based on these results, the inventor files a patent application. Although the application's written description only discloses experimental details for the lemon oil embodiment, it states that the invention "is not limited to the example chosen; other citrus oils, including, but not limited to, orange, lime, citron, and tangerine may be used." The application concludes with the following claim:

> A wood cleaner comprising citrus oil, mineral oil, and white vinegar.

This is considered a generic claim because each embodiment of the invention shares the common characteristic of a citrus oil as an ingredient.[263]

MANAGEMENT 82-85 (2d ed. 2008) (describing the "hierarchy" of patent claims and noting that composition patents are the best for pharmaceuticals).

Second and relatedly, method patents are difficult to enforce because the patentee "acquires only the right to preclude others from using the chemical in the exact manner he has disclosed." Paul H. Eggert, *Uses, New Uses and Chemical Patents—A Proposal*, 51 J. PAT. & TRADEMARK OFF. SOC'Y 768, 781 (1969); *see also* Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 351 (2007) ("Patents on particular methods of treatment involving the use of a drug are generally considered less valuable[] because they cannot be used to stop competitors from selling the same product for other uses.").

262 Seymore, *Heightened Enablement*, *supra* note 61, at 145-46.

263 A generic claim "uses terms that define the invention to include a class of individual embodiments, each of which shares one or more characteristics in common." 1 R. CARL MOY, MOY'S WALKER ON PATENTS § 4.65 (4th ed. 2012).

Now suppose that post-filing experimentation reveals that grapefruit oil does not work. In fact, mixing grapefruit oil with the other ingredients causes the mixture to immediately putrefy.

The applicant cannot allow this claim to stand as filed because its full scope is (known to be) nonenabled. So, the applicant must act. Cancelling the entire claim would go too far because it would unnecessarily give up too much (in fact, all) scope. The best option would be to add a *negative* claim limitation, which is permitted by the courts and the Patent Office as long as it has basis in the original disclosure.[264] For example, the claim can be rewritten with an exclusionary proviso:

> A wood cleaner comprising citrus oil, mineral oil, and white vinegar, *with the proviso that the citrus oil is not grapefruit oil*.

The amendment has a basis in the original disclosure, which describes citrus oils. Importantly, the negative claim limitation works well for the applicant because it only excludes the minimal amount of scope necessary to satisfy the enablement requirement.

Of course, generic claims can be considerably more complex; particularly in pharmaceuticals, chemistry, and biotechnology. To illustrate, suppose that an inventor at a drug company develops a method for making a class of estrogen modulators useful for treating breast cancer. The method requires the reaction of a precursor with a magnesium compound with the generic formula R—Mg—X, where R is an alkyl group (a functional group[265] made up entirely of carbon and hydrogen where the carbon atoms are chained together by single bonds)[266] and X is chlorine or bromine. As filed, the claim recites:

> A method of making a chemotherapeutic comprising . . . reacting [the precursor] with a compound of the formula R—Mg—X, wherein R is an alkyl group and X is Cl or Br.

The claim is actually very broad in scope because there is an infinite number of possible alkyl groups (methyl, ethyl, etc.).[267] Thus, R represents a

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264 *In re* Barr, 444 F.2d 588, 595 (C.C.P.A. 1971), *cited in* MPEP, *supra* note 57, § 2173.05(i) ("The current view of the courts is that there is nothing inherently ambiguous or uncertain about a negative limitation.").

265 A functional group is a group of atoms within a molecule with specific chemical properties that represents a potential reaction site in a compound, thus determining a molecule's chemical reactivity. *See generally* RICHARD C. LAROCK, COMPREHENSIVE ORGANIC TRANSFORMATIONS (2d ed. 1999) (providing examples of functional groups).

266 In chemistry, the symbol R is used to represent a generalized alkyl group. *See* PETER VOLLHARDT & NEIL SCHORE, ORGANIC CHEMISTRY: STRUCTURE AND FUNCTION 72 (7th ed. 2014).

267 *See id.* at 72-75. For example: methyl (one carbon, $—CH_3$); ethyl (two carbons, $—CH_2CH_3$); *n*-propyl (three carbons in a straight chain, $—CH_2CH_2CH_3$), isopropyl (three carbons with a branch, $—CH(CH_3)_2$), etc.

large genus. This style of claiming—where a variable can encompass a large number of alternative species—is ubiquitous in patent law.[268]

Post-filing experimentation reveals that two R—Mg—X combinations do not work. For instance, (1) all reactions with R = ethyl fail to yield a product; and (2) the reaction where R = methyl and X = Cl yields a product that shows no anticancer activity.[269] What should the applicant do? I contend that knowledge of experimental failure requires action since the patent application is still under review. The easiest way is to exclude the inoperable species with an exclusionary proviso:

> A method of making a chemotherapeutic comprising . . . reacting [the precursor] with a compound of the formula *R*Mg*X*, wherein *R* is alkyl and *X* is Cl or Br; *with the proviso that R cannot be an ethyl group and R cannot be a methyl group when X is Cl*.

Although it fair to say that claiming around failure can become tedious or cumbersome for genus claims as the number of species increases, patent applicants routinely use exclusionary provisos,[270] perhaps most often to claim around "prior art."[271] Regardless, the duty to act on known failure should not depend on claim complexity.

V. DISCLOSING FAILURE IN THE PATENT RECORD

While amending the claims to cancel nonenabled subject matter would satisfy the duty of candor and avoid inequitable conduct,[272] it does not solve the file drawer problem.[273] Since an applicant does not have to give a reason for amending or cancelling a claim, an applicant can comply with the law while keeping the details of the experimental failure secret. Although the

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268 *See In re* Driscoll, 562 F.2d 1245, 1249 (C.C.P.A. 1977) (sanctioning the practice). It is referred to as Markush practice. *See In re* Harnisch, 631 F.2d 716, 719-20 (C.C.P.A. 1980) (explaining the history and current law of Markush practice).

269 If a compound is not capable of achieving the asserted use (anticancer activity in the case of the hypothetical), the compound is unpatentable for a lack of utility under § 101. *See In re* Fisher, 421 F.3d 1365, 1370-75 (Fed. Cir. 2005). Such compounds also fail to satisfy the "how to use" prong of the enablement requirement under § 112. *In re* Ziegler, 992 F.2d 1197, 1200-01 (Fed. Cir. 1993).

270 For an example of a patent with several exclusionary provisos, see Hexa- and Heptapeptide Anaphylatoxin-Receptor Ligands, U.S. Patent No. 5,387,671 (filed Dec. 27, 1990) (issued Feb. 7, 1995).

271 *See* Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1453 (Fed. Cir. 1984) (defining prior art as the "knowledge that is available, including what would be obvious from it, at a given time, to a person of ordinary skill in the art"); *see also* 35 U.S.C. § 102(a) (2012) (setting forth the documents and activities that can serve as prior art); Tom Brody, *Negative Limitations in Patent Claims*, 41 AIPLA Q.J. 29, 33-36 (2013) (exploring the use of exclusionary provisos and negative claim limitations to avoid prior art). An invention is compared to the prior art in assessing novelty and nonobviousness.

272 *See supra* Section III.A.

273 *See supra* Section II.B.

claim amendments will prevent the applicant from obtaining a patent of unwarranted scope, a decision not to disclose experimental failure means that this information will not enter the public storehouse of technical knowledge. This has many downsides for the patent system, including low-quality patent examination, creation of nuisance prior art,[274] and thwarted innovation. Encouraging applicants to disclose information about failure in the prosecution history—the public record of the patent proceedings—would solve this problem.[275]

A. *The Post-Filing Information Disclosure Statement*

Adding information about experimental failure to the prosecution history would be easy. Applicants already use a mechanism known as an Information Disclosure Statement (IDS) to disclose information about the invention to the Patent Office.[276] Although the IDS is most often used to comply with the duty of candor owed to the Patent Office,[277] it can be used for a variety of other reasons.[278] And the submission, according to the Patent Office rules, "[would] not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability."[279] This aligns with the Federal Circuit's view that "a patentee should not be 'punished' for being as *inclusive as possible* and *referencing his own work* in an IDS."[280] Thus, the post-filing IDS provides a convenient mode of publicly disclosing experimental failure without the danger of the submitted information being used against the applicant. If anything, as discussed below, the disclosure could actually *help* the applicant.[281]

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274 *See supra* notes 53–54.

275 More specifically, the prosecution history "is the written record of an applicant's dealings with the [Patent Office], including any actions taken by the examiner, and any statements, arguments, or modifications of the claims made by the applicant." DURHAM, *supra* note 19, at 196. The prosecution history contains the record of exchanges between the applicant and the examiner. This includes any information submitted by the applicant or found by the examiner.

276 *See* 37 C.F.R. § 1.97–1.98 (2015) (setting forth the requirements for filing an IDS and for form and content of an IDS). An alternative approach would be to incorporate the details about experimental failure directly into the patent document itself. But this is not as easy as it might seem. The so-called "new matter" doctrine severely restricts post-filing amendments to the disclosure. When an applicant amends the written description, the Patent Office instructs examiners to be on the alert for "new matter." *See* 35 U.S.C. § 132(a) (2012) ("No amendment shall introduce new matter into the disclosure of the invention."); 37 C.F.R. § 1.121 (2015); MPEP, *supra* note 57, § 706.03(o) (alerting examiners).

277 MPEP, *supra* note 57, § 609. For a discussion of the duty of candor, see *supra* Section III.A.

278 For example, the applicant can be transparent and just make sure that the examiner considers the exact same information that the applicant considered. MPEP, *supra* note 57, § 609.

279 37 C.F.R. § 1.97(h), *cited with approval in* Abbott Labs. v. Baxter Pharm. Prods., Inc., 334 F.3d 1274, 1279 (Fed. Cir. 2003).

280 Riverwood Int'l Corp. v. R.A. Jones & Co., 324 F.3d 1346, 1355 (Fed. Cir. 2003) (emphasis added).

281 *See infra* Section V.B. Another scholar has also proposed an expanded role of the IDS with a potential upside for the applicant for additional disclosure. *See* Jay P. Kesan, *Carrots and Sticks to Create a Better Patent System*, 17 BERKELEY TECH. L.J. 763, 769 (2002) (proposing a regime in which an applicant

B. *Incentivizing Full Disclosure*

While all would agree that disclosing negative results with an IDS is good for the patent system, the next question is how to encourage inventor-researchers to disclose them. There is little doubt that disclosure is the biggest hurdle for capturing (and ultimately disseminating) negative information.[282] Overcoming this hurdle is difficult not only because of the file drawer problem,[283] but also because of differences between industrial and academic science,[284] differences within each of the two sectors (and across technical disciplines),[285] and potential trade secret concerns for researchers who change jobs.[286] The challenge is to create

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who provides an IDS that discloses all relevant prior art and discusses how it relates to the claims as filed would receive a patent with a specific presumption of validity with respect to the disclosed prior art).

282 John T. Cross, *Dead Ends and Dirty Secrets: Legal Treatment of Negative Information*, 25 J. MARSHALL J. COMPUTER & INFO. L. 619, 620 (2009) (recognizing the disclosure problem). Nondisclosure or selective disclosure is an enduring problem in patent law. Parchomovsky & Mattioli, *supra* note 67, at 230-31; *see also supra* note 116 and accompanying text.

283 *See supra* Section II.B.

284 Henry Sauermann & Paula E. Stephan, *Twins or Strangers? Differences and Similarities Between Industrial and Academic Science* 3 (Nat'l Bureau of Econ. Res., Working Paper No. 16113, 2010), http://www.nber.org/papers/w16113.pdf ("[W]e find significant differences between the two sectors with respect to the nature of research, the use of various disclosure mechanisms, organizational characteristics, and scientists' preferences."); *see also* DAVID B. RESNIK, THE PRICE OF TRUTH: HOW MONEY AFFECTS THE NORMS OF SCIENCE 41 (2007) (describing the traditional differences between industrial and academic science, including those related to research independence, motivation, and the freedom to decide how and to whom data will be shared).

285 *See, e.g.*, Sauermann & Stephan, *supra* note 284, at 3 (explaining that the differences between academic and industrial practice is smaller in the life sciences than in the physical sciences); *see also* Walter W. Powell & Jason Owen-Smith, *The New World of Knowledge Production in the Life Sciences*, *in* THE FUTURE OF THE CITY OF INTELLECT 107, 107-18 (Steven G. Brint ed., 2002) (noting that unlike other technical disciplines, in the life sciences there is no longer a distinction between basic or applied research, academic or industrial practice, or proprietary or scientific approaches to information disclosure); TAMAS BARTFAI & GRAHAM V. LEES, DRUG DISCOVERY 87 (2006) (explaining that disclosure norms at pharmaceutical companies have evolved to openly and extensively disclose positive results, in part to attract academic collaborators and reassure investors).

286 While a full discussion is beyond the scope of this Article, the drafters of the Uniform Trade Secrets Act believed that negative know-how could be protected as intellectual property. *See* UNIF. TRADE SECRETS ACT § 1 cmt. (amended 1985) (defining "trade secret" to "include[] information that has commercial value from a negative viewpoint, for example the results of lengthy and expensive research which proves that a certain process will *not* work could be of great value to a competitor"). Negative know-how has been described as a "strange[] theory of trade secret law . . . under which an employee who resigns and joins a different business can be liable for not repeating the mistakes and failures of his or her former employer." Charles Tait Graves, *The Law of Negative Knowledge: A Critique*, 15 TEX. INTELL. PROP. L.J. 387, 388 (2007). Graves argues that the doctrine is "conceptually unworkable;" "bestows intellectual property rights in accidents, mistakes, incorrect theories, failed tests, dead ends, and obsolete approaches;" and "[lacks] the usual theoretical justification for intellectual property." *Id.* at 388. To be sure, the case law is split in the handful of states that recognize negative know-how. *See* ROGER MILGRIM, TRADE SECRETS § 1.02[1] (2011) (collecting cases).

specific, practical inducements which would motivate individual researchers to disclose experimental failure.[287]

1. Examination Perks

Perhaps the most basic strategy for incentivizing disclosure is to give the researcher something in return—a quid pro quo. Of course, this rationale incentivizes the disclosure of information that the public might not otherwise get.[288] For the patentee, the incentive for full public disclosure of the invention is the limited period of exclusionary rights.[289] For the public, the exchange serves the public good because the disclosed information enriches the public storehouse of technical knowledge once the patent document publishes.[290]

One way to combat the file drawer problem is to provide applicants who disclose failure with some perk during patent examination. Perks like fee reductions[291] and accelerated examination[292] seem feasible because the Patent Office and Congress already use such measures to achieve certain policy objectives.[293]

But disclosing failure could confer an even more important benefit to the applicant. It is no secret that applicants know more about their inventions

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287 *Cf.* Patil & Siegel, *supra* note 97, at 522 ("[A]lthough the arguments in favor of [publishing negative results] all seem to revolve around benefits to the community, the costs of [disclosure] would fall on individual authors. If the community is to reap the benefits, then the costs to the individual authors must be driven to zero—or associated with some reward.").

288 EDWARD C. WALTERSCHEID, THE NATURE OF THE INTELLECTUAL PROPERTY CLAUSE 143 (2002).

289 *See* J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 142 (2001) ("The disclosure required by the Patent Act is the *quid pro quo* of the right to exclude." (quoting Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 484 (1974)) (internal quotation marks omitted)); *Kewanee*, 416 U.S. at 480-81 (describing the quid pro quo that supports the patent grant as a constitutional objective).

290 *See supra* notes 55 and 72 and accompanying text.

291 For example, Congress has directed the Patent Office to reduce fees for independent inventors and other small entities. *See* 35 U.S.C. § 41(h)(1) (2012) (mandating a fifty percent reduction). One statutory objective of this perk is to provide incentives to invent and patent. *See* H.R. REP. NO. 102-382, at 13 (1991), *as reprinted in* 1991 U.S.C.C.A.N. 1320, 1328 (explaining that "the small entity fee structure is important to encourage innovation in the United States" because without it, independent inventors "would be disinclined to protect their inventions because of a lack of resources.").

292 *See* Changes to Practice for Petitions in Patent Applications to Make Special and for Accelerated Examination, 71 Fed. Reg. 36,323, 36,323 (June 26, 2006) (describing a program which allows applicants to accelerate examination to one year).

293 *See, e.g.*, Cancer Immunotherapy Pilot Program, 81 Fed. Reg. 42,328, 42,328 (Jun. 29, 2016) (implementing a pilot program which offers fast track examination for applications claiming a method of treating cancer using immunotherapy).

than examiners,[294] who tend to suffer from an information deficit.[295] So an applicant who is transparent about failure not only gives the examiner a more accurate picture of the invention landscape,[296] but does much to build a better relationship with the examiner.[297] The applicant's ultimate benefit is the possibility of more (or broader) allowed claims. The public benefits too, as transparency and full disclosure lead to higher-quality patent examination and, ultimately, higher-quality patents.

2. Defensive Publication

The ability to control the technological landscape can provide a strong incentive to disclose negative results. For instance, disseminating negative results helps coordinate the future development of technology by reducing duplicative research efforts and providing technical fodder, which can spur additional inventive activity.[298] But this is only part of the story. Given that negative results can potentially defeat patentability,[299] their dissemination can be used strategically to control the patent landscape around the disclosed information. Thus, a research organization might engage in defensive publication, which occurs when information is "intentionally made available to the public as prior art in order to render any subsequent claims of invention

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294 *See* Joseph Scott Miller, *Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents*, 19 BERKELEY TECH. L.J. 667, 734 (2004) (explaining that applicants "know better than [the Patent Office or] anyone else precisely what it is they have developed or invented."); *see also* Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341, 1357 (Fed. Cir. 2008) (noting that "the patent practice includes recognition that the inventor usually knows more about the field than does the 'expert' patent examiner").

295 Seymore, *Patent Asymmetries*, *supra* note 15, at 991-94.

296 *See supra* note 136 and accompanying text.

297 Although patent examination is considered as a non-adversarial proceeding, the applicant and examiner have different objectives. Whereas the applicant wants a patent with broad claims, the "examiner ostensibly represents the public in ensuring that the patent applicant does not obtain rights to information that properly belongs in the public domain under the patentability standards." Kelly C. Mullally, *Patent Hermeneutics: Form and Substance in Claim Construction*, 59 FLA. L. REV. 333, 346 (2007). Examiners carry out this task by ensuring that claims are "examined, scrutinized, limited, and made to conform to what [the applicant] is entitled to." Keystone Bridge Co. v. Phoenix Iron Co., 95 U.S. 274, 278 (1877).

298 *See infra* subsection V.C.2.

299 *See supra* note 135 and accompanying text. For example, a prior art reference that discloses a failed experiment can be used to support a conclusion that an invention lacks nonobviousness. Symbol Techs., Inc. v. Opticon, Inc., 935 F.2d 1569, 1578 (Fed. Cir. 1991); *see also* Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1357 (Fed. Cir. 2003) ("Under § 103 . . . a reference need not be enabled; it qualifies as a prior art, regardless, for whatever is disclosed therein."). It is reasonable to expect that a PHOSITA will turn to other references, in addition to knowledge and skill in the relevant technical field, to fill in the technical gaps to make the invention with a reasonable expectation of success. *See, e.g.*, Purdue Pharma Prods. L.P. v. Par Pharm., Inc., 377 Fed. App'x 978, 982-83 (Fed. Cir. 2010) (explaining in the § 103(a) context, though one reference was nonenabled, the PHOSITA could have achieved the claimed invention through routine experimentation).

or discovery ineligible for a patent."[300] With negative results, the expectation is that publishing them will create an insurmountable obviousness hurdle around the disclosed information.[301]

The importance of defensive publication as a strategic tool cannot be overstated.[302] Research organizations use it as a low-cost mechanism for both preventing competitors from obtaining patents and for guaranteeing the organization's freedom to practice:

> [A]s the costs of patent applications and litigation continue to rise[,] defensive publishing is offering scientists another option: by making published descriptions of their innovative research products available to the public, they prevent others from patenting them, thus they ensure the results' continued availability without incurring the significant legal and filing fees involved in patenting.[303]

Thus, defensive publication can serve as a key element in a research organization's overall intellectual property management strategy.[304]

Venues for defensive publication abound. They include company-generated prior art journals,[305] commercial prior art websites,[306] peer-

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300 STEPHEN A. HANSEN & JUSTIN W. VANFLEET, TRADITIONAL KNOWLEDGE AND INTELLECTUAL PROPERTY 24 (2003); *see also* Scott Baker & Claudio Mezzetti, *Disclosure as a Strategy in the Patent Race*, 48 J.L. & ECON. 173, 175 (2005) (explaining that defensive publications "are designed to preempt patents in instances in which the disclosing firm does not itself plan to pursue patent protection but fears that its rivals might.").

301 Baker & Mezzetti, *supra* note 300, at 176. *See also supra* note 299.

302 *See, e.g.*, Douglas Lichtman et al., *Strategic Disclosure in the Patent System*, 53 VAND. L. REV. 2175, 2175-76 (2000) (discussing a firm's strategic incentive to create prior art); Gideon Parchomovsky, *Publish or Perish*, 98 MICH. L. REV. 926, 927 (2000); *see also* Bill Barrett, *Defensive Use of Publications in an Intellectual Property Strategy*, 20 NATURE BIOTECH. 191, 191-93 (2002) (providing specific drafting strategies for creating prior art).

303 Stephen Adams & Victoria Henson-Apollonio, INT'L SERV. FOR NAT'L AGRIC. RES. BRIEFING PAPER NO. 53, DEFENSIVE PUBLISHING: A STRATEGY FOR MAINTAINING INTELLECTUAL PROPERTY AS PUBLIC GOODS, at 2 (2002), http://ebrary.ifpri.org/cdm/ref/collection/p15738coll11/id/296 [https://perma.cc/D2C5-MN88] (citing Richard Poynder, *On the Defensive About Invention*, FIN. TIMES (London) (Sept. 19, 2001), http://www.richardpoynder.co.uk/On%20the%20defensive.htm [https://perma.cc/3M87-4HAG]).

304 *Id.* Indeed, defensive publication can be "a 'spoiler' tactic—you disclose your technology without pursuing patent protection for yourself just to be sure that no-one else can have a patent for it either." Anthony Murphy, *Intellectual Property*, *in* INNOVATION: HARNESSING CREATIVITY FOR BUSINESS GROWTH 89, 92 (Adam Jolly ed., 2003).

305 Famous examples include the *Bell Laboratory Record*, *IBM Technical Disclosure Bulletin*, *Siemens Zeitschrift*, and *Xerox Disclosure Journal*. ADAMS & HENSON-APOLLONIO, *supra* note 303, at 5. Companies often distribute the journals to the Patent Office and commercial databases. *Id.*; Baker & Mezzetti, *supra* note 300, at 174.

306 The two most popular sites are Research Disclosure and IP.com. Research Disclosure, "the industry standard defensive publication service," asserts that "over 90% of the world's leading technology companies" have used its services. *About Research Disclosure*, RESEARCH DISCLOSURE, http://www.researchdisclosure.com/about-research-disclosure [https://perma.cc/8C65-VPEX]. IP.com's

reviewed literature,[307] and patent documents.[308] These venues vary widely in financial cost, the human investment required to prepare them, timeliness, and accessibility.[309] Clearly, the incentive to defensively disclose is strengthened when the publication venue is cheap, easy to produce, timely, and easy for the patent examiner to find during a prior art search.[310] Since an IDS easily satisfies all four criteria, it could easily become an attractive medium for defensive publication.

C. *Normative Implications*

Admittedly providing incentives for patent applicants to disclose failure is a challenge. Below I explain why disclosure of failure in the prosecution history should become the norm.

1. On Patent (Examination) Quality

The Patent Office is often criticized for making awful patenting decisions which lead to the proliferation of low-quality patents.[311] Aside from being invalid,[312] patents that fail to meet the statutory standards of patentability are often worthless and burdensome on the patent system.[313]

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prior art database is "the first and largest online prior art disclosure service and the only one publicly available." *See* Who We Are, IP.COM, https://ip.com/who-we-are/ [https://perma.cc/X8AM-LTHN].

307 For a discussion of peer-reviewed literature, see *supra* notes 106-107 and accompanying text.

308 It is often forgotten that the patent document serves several key roles in the patent system. Most prominently, the claims establish the boundaries of the patentee's right to exclude, 35 U.S.C. § 112(b) (2012), which expires twenty years from the earliest effective filing date, § 154(a)(2). But in addition, the disclosure (the written description and the drawings) of a patent or published patent application can serve as prior art. *Id.* § 102(a). A patent is effective as prior art as of its filing date and remains so forever (just like a book, a magazine, or any other printed publication). *See id.* § 102(a)(2) (providing that an invention is not patentable if it is described in a patent or patent application by another inventor and effectively filed before the before the effective filing date of the claimed invention). So the basic idea is to disclose information in the patent document but not claim it. The disclosed-but-unclaimed subject matter will become prior art.

309 *See* ADAMS & HENSON-APOLLONIO, *supra* note 303, at 7 (presenting a table which compares the various defensive publication mechanisms); *see also* Poynder, *supra* note 303 (explaining that the "$109 (£75) per document [cost] to publish on IP.com . . . compares very favorably with the $20,000 it costs per patent application to file in key locations worldwide" (internal quotations omitted)). Another consideration is whether the cost of defensive publication is cheaper than potential litigation. *See* HANSEN & VANFLEET, *supra* note 300, at 24 ("[T]he costs (both personal and financial) of making a defensive disclosure need to be weighed against the cost of not making that disclosure, specifically the costs of challenging a patent that would not have been granted had the disclosure been made." (citation omitted)).

310 *Cf.* ADAMS & HENSON-APOLLONIO, *supra* note 303, at 3-7 (listing the factors to consider when choosing a mechanism for defensive publication; including accessibility, timeliness, and cost).

311 *See supra* notes 1-2 and accompanying text.

312 *See supra* note 7.

313 *See supra* note 8; Bronwyn H. Hall & Dietmar Harhoff, *Post-Grant Reviews in the U.S. Patent System—Design Choices and Expected Impact*, 19 BERKELEY TECH. L.J. 989, 992 (2004) (explaining that the costs of low quality patents "include entry deterrence of would-be innovators, a slower pace

A high-quality patent examination requires good information about the invention and the technological landscape.[314] Several commentators argue that one of the primary causes of the quality problem is that examiners lack adequate technical information needed to perform a rigorous examination.[315] Given that examiners draw heavily from materials found in patent databases,[316] there is a good chance that examiners will overlook information not found there. This is particularly problematic in nascent, rapidly-changing, or highly-specialized fields where there is a paucity of relevant patent literature.[317] So to the extent that examiners are unlikely to turn to nonpatent literature in gauging patentability, information that is not in the prosecution history will probably not be considered.

Technical information about failure is extremely important in gauging patentability—specifically, in determining whether an invention is novel, nonobvious, and enabled.[318] Thus, moving toward a disclosure paradigm where failure is disclosed in the prosecution history could dramatically improve patent quality. And to be clear, disclosing failure in one case would not only be considered in gauging the patentability of the invention claimed in that application, but could be considered for other inventions in other applications.[319] So the availability of an expanded universe of technical information (which includes failure) would allow examiners to conduct a more robust examination of applications and ultimately improve the quality of issued patents.

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of innovation, and increases in patent application activity that are costly both to the firms and to society"); John R. Thomas, *The Responsibility of the Rulemaker: Comparative Approaches to Patent Administration Reform*, 17 BERKELEY TECH. L.J. 727, 731 (2002) (explaining that legal actors often must revisit the Patent Office's work to assess patent validity).

314 *See supra* note 10 and accompanying text.

315 JAFFE & LERNER, *supra* note 1, at 139; *see also* Lemley, *Rational Ignorance*, *supra* note 8, at 1500 ("[M]uch of the most relevant prior art isn't easy to find—it consists of [third-party activities] that don't show up in any searchable database and will not be found by examiners in a hurry."); Michael Risch, *The Failure of Public Notice in Patent Prosecution*, 21 HARV. J.L. & TECH. 179, 196 (2007) ("A high-quality prior art search is difficult because of resource and time limitations."); John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 U. ILL. L. REV. 305, 318-19 [hereinafter Thomas, *Collusion*] (explaining that in newer technologies, examiners often cannot obtain the most recent technical literature).

316 *See* John R. Allison & Mark A. Lemley, *The Growing Complexity of the United States Patent System*, 82 B.U. L. REV. 77, 102 (2002) ("The predominance of citations to U.S. patents [as cited prior art] may . . . reflect the limitations of the PTO systems for searching: the PTO is much more likely to find documents that it itself has generated."); Thomas, *Collusion*, *supra* note 315, at 318 ("In comparison to much of the [non-patent] literature, patents are readily accessible, conveniently classified and printed in a common format. Identification of a [non-patent] reference, and full comprehension of its contents, often prove[s] to be more difficult . . . .").

317 Thomas, *Collusion*, *supra* note 315, at 318-19 ("Overreliance upon patents as indicia of the state of the art works far more mischief in fields long believed to be outside the patent system [like software and other postindustrial inventions, where] the repository of issued patents insufficiently samples the prior art.").

318 *See supra* note 2 (listing the substantive patentability requirements).

319 *Cf.* Parchomovsky & Mattioli, *supra* note 67, at 230 ("It should be borne in mind that information about failed research in a particular industry may be useful to inventors in other industries as well.").

2. On Technological Progress

Both patent law and science promote technological progress through the dissemination of knowledge.[320] For instance, in patent law there is hope that the public will use the technical information disclosed in a patent document to improve upon the invention, design around it, or to spur more innovation.[321] Science contemplates that researchers will engage in similar activities upon reading a technical publication.[322] Of course, the two differ in their mechanisms of knowledge transfer. Whereas patent law emphasizes the quick dissemination of technical knowledge to the public[323] (in part because of its indifference to ancillary details like the inventor's identity or acumen),[324] science insists on filtering knowledge through a legitimization process known as peer review.[325] Thus, the two disseminate knowledge in related, though dissimilar, ways.

Yet the two spheres have much in common when it comes to the role of disclosure in achieving certain objectives. For example, in both spheres there is hope that the disclosed information will actually enrich the public storehouse of technical knowledge.[326] This is why, at a minimum, both patent

320 Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 180 (1987). In particular, both mainstream science and patent law promote disclosure through publication. Once in the public domain, there is hope that others will build upon those results and engage in further research. *See id.* at 184. But Professor Eisenberg also points out that to the extent that patent protection "limit[s] the ability of other scientists to use published knowledge, intellectual property law has been perceived within the scientific research community as conflicting with the traditional norms and rewards of science." *Id.*; *see also* Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1017 (1989) ("Yet the idea that exclusive rights in new knowledge will promote scientific progress is counterintuitive to many observers of research science, who believe that science advances most rapidly when the community enjoys free access to new discoveries.").

321 Seymore, *Teaching Function*, *supra* note 51, at 632; *see also* MICHAEL A GOLLIN, DRIVING INNOVATION 15-19 (2008) (explaining that disclosure adds to the pool of accessible knowledge that other creative individuals can use and improve upon).

322 Seymore, *Teaching Function*, *supra* note 51, at 663 (citations omitted).

323 The statutory scheme helps achieve this goal. For example, a pre-filing disclosure generally defeats patentability, although there are limited exceptions for disclosures made by or derived from the inventor. *See* 35 U.S.C. § 102(b). To aid in quick dissemination, most patent applications publish eighteen months after filing. *See id.* § 122(b)(1)(A).

324 *See* Eames v. Andrews (The Driven-Well Cases), 122 U.S. 40, 56 (1887) (explaining that an inventor's ignorance of the scientific principles is immaterial as long as the patent's disclosure sets forth the "thing" to be done so that it can be reproduced); *see also* Radiator Specialty Co. v. Buhot, 39 F.2d 373, 376 (3d Cir. 1930) ("It is with the inventive concept, the thing achieved, not with the manner of its achievement or the quality of the mind which gave it birth, that the patent law concerns itself."); Earle v. Sawyer, 8 F. Cas. 254, 256 (C.C.D. Mass. 1825) (No. 4,247) (Story, J.) ("It is of no consequence, whether the thing be simple or complicated; whether it be by accident, or by long, laborious thought . . . that it is first done [because the] law looks to the fact, and not to the process by which it is accomplished.").

325 This process ensures that each research claim is reproducible, logical, independent, and satisfies other basic conditions for communal acceptability. JOHN M. ZIMAN, REAL SCIENCE 246 (2002). For a discussion of the mechanics of peer review, see *supra* notes 106–107 and accompanying text.

326 *See supra* note 55.

law and science require a disclosure that teaches something that is novel, nontrivial, and reproducible by skilled artisans in the technical field.[327]

The disclosure function works best when an inventor or researcher tackling a given problem can get a *complete picture* of the relevant accumulated knowledge. Knowing the lay of the land promotes the efficient allocation of resources.[328] But concealment of experimental failure prevents this from happening in at least two ways. First, other researchers might waste resources on duplicative efforts (trying to develop something that has already been attempted—albeit unsuccessfully) rather than working on more productive activities.[329] Second, ignorance of failure might lead some researchers to avoid risky endeavors or those with uncertain outcomes and instead "be overly conservative, perhaps even wasting societal resources on too-safe technology that might be spent on other human endeavors or social needs."[330] In both patent law and science, this waste impedes, rather than promotes, technological progress.

Advancing knowledge—and technology—via full disclosure is a firmly-held goal shared by patent law and science.[331] Disclosing experimental failure helps achieve this goal because it provides substantive technical knowledge from which others can learn.[332] Recall that failed experiments always yield *something*—whether it be a serendipitous result,[333] an abundance of unexpected technical data, or simply knowledge that an initial hypothesis was totally wrong.[334] There is hope that someone can extract knowledge from failure and use it to achieve success with the failed experiment or for other creative purposes.[335]

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327 Seymore, *Teaching Function*, *supra* note 51, at 663 (citations omitted).

328 Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. LEGAL STUD. 247, 262-67 & n.79 (1994).

329 *See supra* notes 121–139 and accompanying text; F. Scott Kieff, *The Case for Registering Patents and the Law and Economics of Present Patent-Obtaining Rules*, 45 B.C. L. REV. 55, 99-100 (2003) (describing how disclosure can coordinate downstream activities, including the prevention of duplicative efforts).

330 Henry Petroski, *The Success of Failure*, 42 TECH. & CULTURE 321, 328 (2002).

331 *See supra* note 72; Bernice T. Eiduson, *Psychological Aspects of Career Choice and Development in the Research Scientist*, *in* SCIENCE AS A CAREER CHOICE: THEORETICAL AND EMPIRICAL STUDIES 3, 24 (Bernice T. Eiduson & Linda Beckman, eds., 1973) ("A scientist . . . is constantly reminded . . . that it is his job to advance knowledge by some increment, large or small."); ROBERTA NESS, THE CREATIVITY CRISIS: REINVENTING SCIENCE TO UNLEASH POSSIBILITY 73 (2015) (noting that one of the noble goals of science is "to advance knowledge for the good of society" (internal citation omitted)).

332 *See supra* Section II.A.

333 *See* FIRESTEIN, *supra* note 93, at 44-45 (explaining serendipitous discoveries that come from failure; that is, "[s]omething doesn't work the way you thought it should and exploring the reasons for that leads to the initially unexpected and now surprising result."). *See generally* Sean B. Seymore, *Serendipity*, 88 N.C. L. REV. 185 (2009) (exploring accidental discoveries in patent law and their alignment with the substantive law of invention).

334 *See supra* notes 129–133 and accompanying text; Matosin et al., *supra* note 101, at 173 (explaining that research should be a "systematic, hypothesis-driven attempt[] to fill holes in our knowledge," which means reporting failure and developing a new hypothesis which "provide[s] an explanation as to why we are seeing what we are seeing.")

335 FETZER, *supra* note 95, at 16.

CONCLUSION

It is perhaps inevitable that the Patent Office will issue patents that are partially inoperable—that is, patents that claim some subject matter that does not work as described. These patents contribute to the patent quality problem and impose costs on the courts, competitors, would-be inventors, and society. Scholars posit that fixing the problem would require more rigorous (and costly) patent examination[336] or perhaps heightened patentability standards.[337] But they have completely overlooked the paradigm presented in this Article: when the inventor learns after filing that some of the claimed subject matter does not work and chooses to conceal that information from the Patent Office. When this happens, it is not at all surprising that a partially inoperable patent will issue. There is every reason to believe that concealment of inoperability is pervasive, thereby producing a countless number of issued patents which disclose and claim failure.

But this cannot be right. Despite the murkiness of the relevant case law, this Article has explained why an inventor cannot conceal known failure without breaching a duty of candor and good faith owed to the Patent Office. The inventor must act, at a minimum, by claiming around the failure. But the patent system should also encourage inventors who learn about failure after filing to add this information to the patent record. Such post-filing disclosures would dramatically improve patent examination, reduce uncertainty (about what works and what does not work), and make the patent document a more robust source of technical information. Thus, this regime would ultimately improve patent (examination) quality and promote broader goals of the patent system.

336 *See, e.g.*, Michael J. Meurer, *Patent Examination Priorities*, 51 WM. & MARY L. REV. 675, 706-07 (2009) (proposing an examination regime which allows the Patent Office to devote more time and resources to applications in certain technologies); John M. Golden, *Proliferating Patents and Patent Law's "Cost Disease"*, 51 HOUS. L. REV. 455, 490-98 (2013) (advocating an examination regime that includes work sharing with foreign patent offices or privatizing or automating application review). *But see* Lemley, *Rational Ignorance*, *supra* note 8, at 1510-11 (arguing against investing more resources in substantive patent examination as a means of improving patent quality because most patents are never asserted, litigated, or licensed).

337 *See, e.g.*, BESSEN & MEURER, *supra* note 1, at 162-63 (exploring the decline in patent quality and attributing the weakening of patentability standards to the Federal Circuit); JAFFE & LERNER, *supra* note 1, at 11, 201 (same).